ADVANCE MARKET COMMITMENT FOR PNEUMOCOCCAL VACCINES

Annual Report

1 April 2010 – 31 March 2011

Prepared by the GAVI Alliance Secretariat

Contents

Abbreviations

AMC	Advance Market Commitment
AMT	AVI Management Team
AVI	Accelerated Vaccine Introduction
EC	GAVI Executive Committee
FOC	Firm Order Commitment
GAVI	GAVI Alliance
GNI	gross national income
IAC	Independent Assessment Committee
IRC	Independent Review Committee
M&E	monitoring and evaluation
NRA	national regulatory authority
NVS	new vaccine support
PATH	Program for Appropriate Technologies for Health
PCV	pneumococcal conjugate vaccine
PRG	Procurement Reference Group
PSA	Provisional Supply Agreement
PSF	Product Summary File
QSS	WHO Quality Safety and Standard division
SCIH	Swiss Centre for International Health
SDF	Strategic Demand Forecast
TPP	Target Product Profile
UNICEF	United Nations Children's Fund
WHO	World Health Organization

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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 implementation of the pneumococcal AMC started with the signature of the AMC legal agreements on 12 June 2009. Since then, GAVI and partners have been working towards the introduction of pneumococcal vaccines in GAVI-eligible countries.

The purpose of the report is to provide an update on AMC implementation activities, including procurement activities, activities to facilitate vaccine introduction, delivery of vaccines, the work of the Independent Assessment Committee (IAC), monitoring and evaluation activities, media and communications work, and all financial reporting.

The first pneumococcal AMC Annual Report was published on the AMC website on 4 May 2010. This report provided an overview of the AMC structure and processes and also presented all activities linked to the implementation of the pneumococcal AMC since the signature of the AMC legal agreements on 12 June 2009 until the 31 March 2010[a].

This second progress report covers all activities from 1 April 2010 to 31 March 2011 which saw the first introductions of pneumococcal vaccines in GAVI countries. The report was developed by the AMC Secretariat at GAVI, in collaboration with the World Bank and UNICEF Supply Division (SD), and was approved by the Independent Assessment Committee on 23 April 2011[b].

[a] Available on the AMC website: http://vaccineamc.org/files/PneumoSDFv1_8_7_09.pdf
[b] Note that as a public document, this report does not include any confidential information.

1. Revision of the AMC legal agreements

In light of experience from the first year of implementation of the pneumococcal AMC, GAVI, the World Bank and UNICEF – the "AMC implementing agencies" – identified a series of modifications to the AMC legal agreements in order to ensure greater efficiency in the operation of the pneumococcal AMC (see Annex 1).

These suggested modifications were presented to the AMC Stakeholders during the AMC Stakeholder Meeting on 17 June 2010 and subsequently approved on 6 July 2010.The AMC Secretariat, together with UNICEF Supply Division, also notified all AMC Registered Manufacturers of these changes late February 2011. In addition, the modifications to the IAC Charter and Bylaws were approved by the IAC on 10 February 2011.

The execution copies of the revised legal agreements were signed by the World Bank and GAVI on 7 March 2011 and published on the AMC website on 10 March 2011.

2. Procurement and introduction activities

2.1. Implications of GAVI's new policies

The GAVI Board decisions of November 2009 on the newly adopted eligibility[1] and graduation policies[2] resulted in a decrease of the forecasted GAVI demand for vaccines and, consequently impacted the AMC programme[c]. In addition, the Board required that only countries whose DTP3 coverage is above 70% would be eligible for new vaccines support, including pneumococcal vaccines.

However, a number of subsequent decisions by the Board helped mitigate the impact. First, in June 2010, the GAVI Board approved the grandfathering of the AMC such that all countries that were eligible for GAVI support at the time of signature of the AMC legal agreements – in June 2009 – are still able to access pneumococcal vaccines through GAVI at the AMC terms and conditions[3].

Further, in July 2010, the Executive Committee (EC) decided to allow countries graduating from GAVI support at the end of 2010 to have a final opportunity to apply for GAVI support in May 2011[4] (see Figure 3).

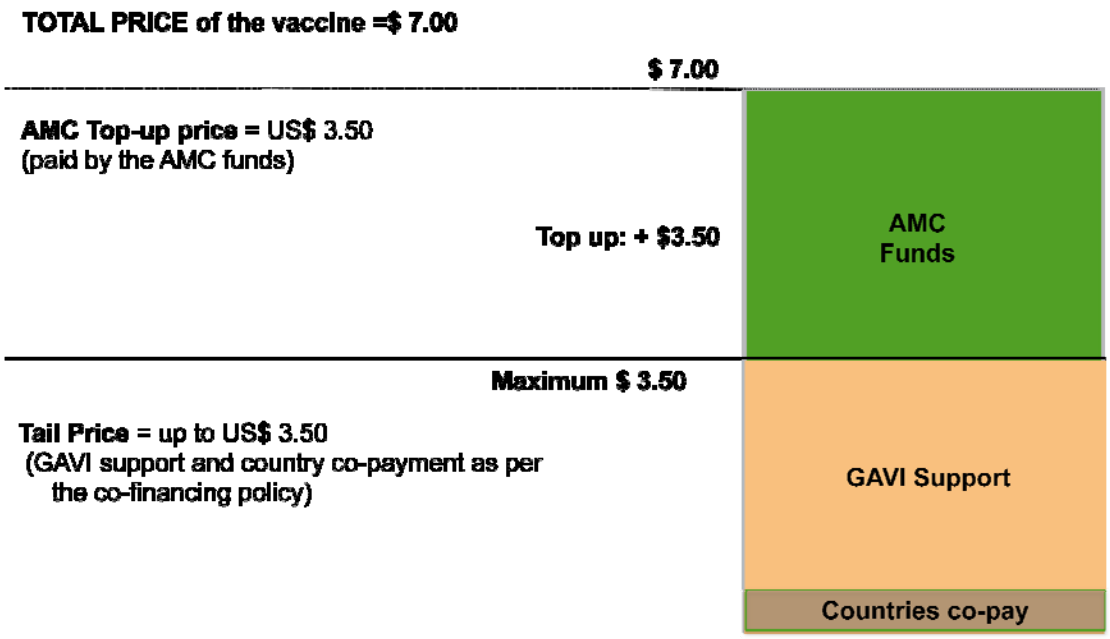
Finally in December 2010, the Board decided to suspend their decision to raise GAVI's DTP coverage filter to 70% for May 2011, so that countries whose DPT3 coverage is above 50% could still apply for any new vaccines application round.

In summary:

- GAVI-eligible countries whose DTP3 coverage is above 70% - or above 50% for the May 2011 application round only - can apply for GAVI support for the introduction of pneumococcal vaccines through the GAVI application process. Provided that applications are approved, the countries will receive GAVI support and will contribute to the cost of the vaccine according to GAVI co-financing policy (see Figure 1).

[c] As a result of the revised eligibility criteria, 16 countries are graduating from GAVI support in 2011 because their GNI per capita exceeds the new eligibility threshold of US$ 1,500. The list of GAVI-eligible countries is available in Annex 2.

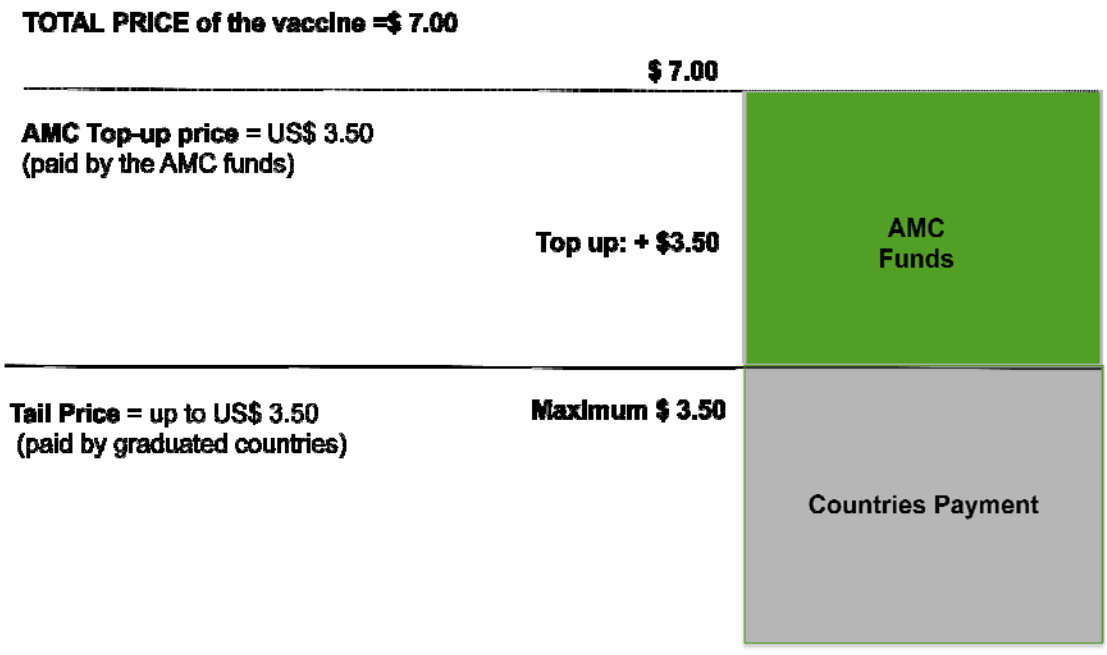
Figure 1. Funding of pneumococcal vaccines with GAVI support



Source: GAVI Alliance Secretariat

- From 2012, graduated countries (i.e. countries that are no longer eligible for GAVI support because their Gross National Income (GNI) per capita is above US$ 1500) with a DTP3 coverage above 70% who have not yet received support from GAVI will still be able to access pneumococcal vaccines through GAVI at the AMC terms and conditions and have access to AMC funding. However these countries will need to completely self finance the vaccine price (tail price) (see Figure 2).

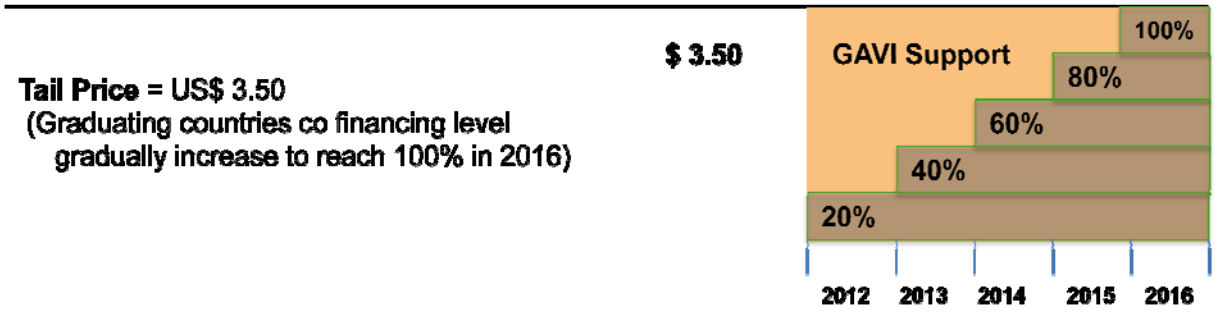
Figure 2. Funding of pneumococcal vaccines for graduated countries.



Source: GAVI Alliance Secretariat

- Figure 3 illustrates the funding of pneumococcal vaccines for the countries graduating from GAVI support in 2011.

Figure 3. Funding of pneumococcal vaccines for graduating countries



Source: GAVI Alliance Secretariat

2.2. Strategic Demand Forecasts

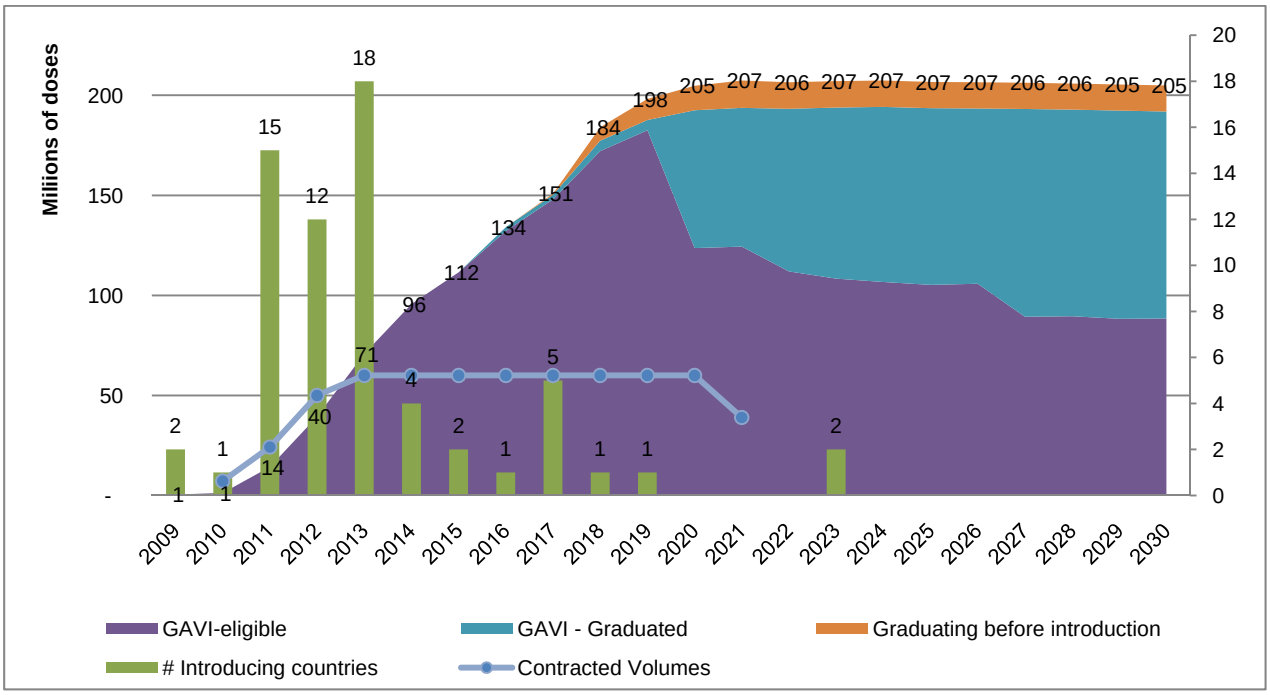
According to the AMC Terms and Conditions[5], the GAVI Alliance shall publish an updated Strategic Demand Forecast (SDF) on the AMC Website annually. The SDF outlines estimated demand for pneumococcal vaccines, estimated supply and the unmet demand. Based on the unmet demand, UNICEF may issue Calls for Supply Offers.

SDF version 0.1 was published on the AMC website on 7 August 2009[6] and served as basis for the first Call for Supply Offers issued in September 2009.

SDF v2.0 was presented to the GAVI Board in December 2010. The GAVI Board decisions described in section 2.1 led to significant changes to the SDF. As such, GAVI and UNICEF SD agreed to delay publication to allow for appropriate revision.

The SDF v3.0 was published on the AMC website on 11 March 2011. The estimated required supply is summarised in figure 4.

Figure 4. Pneumococcal vaccine required supply – SDF v3.0



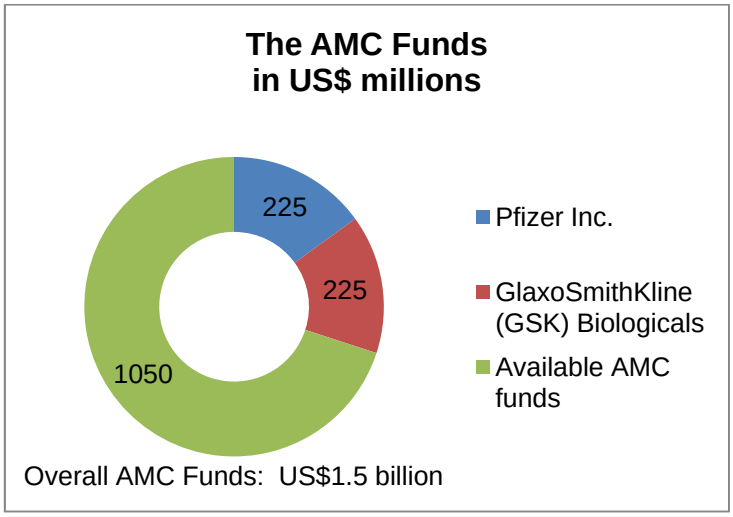
Source: GAVI Alliance Secretariat

2.3. Call for Supply Offers

The first procurement cycle for the supply of pneumococcal vaccines under the AMC was initiated with the publication 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 (GSK) Biologicals and Pfizer Inc – the only companies whose Product Summary File (PSF) had been accepted by WHO for prequalification review. Both manufacturers committed to supply 30 million doses each starting respectively in January 2012 and January 2013.

Consequently, 15% of AMC funds were allocated to each manufacturer. As of 31 March 2011, 70% of the AMC funds remain available for allocation (see Figure 5).

Figure 5. Status of allocation of AMC funds, as of 31 March 2011 (US$ millions)



Source: GAVI Alliance Secretariat

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[d]. Both suppliers have subsequently communicated the ability to increase such early supplies, should there be demand.

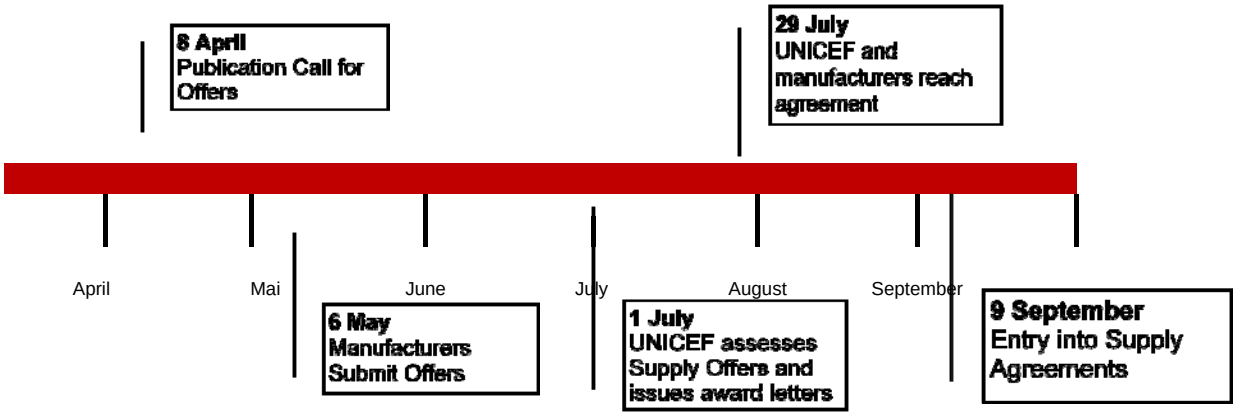
Both GSK and Pfizer's products received WHO prequalification in 2010 and were deemed AMC Eligible by the AMC Independent Assessment Committee (IAC) respectively on 16 April 2010 and 23 August 2010. This was communicated to suppliers with a copy to UNICEF on 6 May 2010 and on 23 August 2010. As a result the PSAs automatically turned into effective Supply Agreements, allowing the procurement of those two vaccines (also see section 4.2.1).

Following the publication of SDF v3.0, GAVI, in consultation with UNICEF, decided to issue a new Call for Supply Offers for the procurement of pneumococcal vaccines. UNICEF therefore organised a pre-tender meeting on 10 March 2011 in Copenhagen to inform manufacturers about the AMC concept, including available funding for future contracts, the requirements for the forthcoming call and to provide an update on the introduction of pneumococcal conjugate vaccines (PCV) in GAVI countries and subsequent demand.

A new Call for Supply Offers is scheduled to be published on 8 April 2011. UNICEF will assess offers received and will consult with a Procurement Reference Group[7] (PRG) for advice on evaluation of bids, structuring of awards and allocation of supply. As per the timelines set out in the AMC legal agreements, UNICEF will then send award letters to selected manufacturers on 1 July. This could allow for signature of supply agreements by September 2011 (see Figure 6).

[d] 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.

Figure 6. 2011 AMC procurement timeline



Source: UNICEF Supply Division

Given that the next applications for new vaccine support (NVS) are due by 15 May 2011 and are scheduled for financial approval by the Executive Committee (EC) during its meeting in September, the timing for entry into supply agreements as outlined above is expected to allow for supply to newly approved countries from Q1 of 2012.

2.4. Availability of pneumococcal vaccines

As of 31 March 2011, there are currently two pneumococcal conjugate vaccines (PCV) available for procurement under the AMC:

2.4.1. Pneumococcal conjugate vaccine, 10-valent

GlaxoSmithKline launched a 10-valent PCV (PCV10) in Europe in 2009. PCV10 is a liquid vaccine in a novel presentation, as it is supplied in a 2 dose vial without preservative. Therefore, both doses are intended to be used within 6 hours of the vial being opened. This presentation requires that staff is trained to ensure that the vaccines are used safely - i.e. technique to be used to withdraw multiple doses from one container, how to handle vials, and to discard unused doses after 6 hour maximum from extraction of the first dose. The 2 dose presentation obtained WHO prequalification on 12 March 2010. However, due to the novelty of its presentation, the pre-qualification was first limited to Kenya until successful completion of a 12 months assessment of programmatic issues in two demographic surveillance sites[8].

On 16 April 2010, the AMC Independent Assessment Committee (IAC) reviewed GSK's application for AMC eligibility and deemed that the candidate vaccine was eligible for purchase pursuant to the terms and conditions of the AMC. Notification of the decision was sent to the supplier with a copy to UNICEF Supply Division on 6 May 2010. UNICEF Supply Division was thus able to start the procurement of PCV10 to Kenya in September 2010 (also see section 4.2).

Based on information on availability of additional supply early 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, prior to data from the use of the novel presentation becomes available. The Committee approved the use of PCV10 to other countries provided that the following criteria are met by the supplier and recipient countries:

- Specific labelling indicating in red text "Discard open vial after 6 hours";
- Cooperation with and support for WHO EPI group on development and implementation of a training programme for and supply of materials to immunisation staff;
- Cooperation with and support for WHO EPI group to monitor the introduction of the vaccine through repeated cluster sampling surveys followed by a complete Post-Introduction Evaluation;
- Implementation of a Phase IV study to monitor Adverse Events following Immunisation (AEFIs) associated with potential mishandling of the product.

Ethiopia has expressed interest in establishing such structure to allow introduction of PCV10 in 2011. WHO is working closely with the country to support them to realise their plans.

2.4.2. Pneumococcal conjugate vaccine, 13-valent

PCV13 in 1-dose vials obtained WHO prequalification on 22 August 2010. On 23 August 2010, the AMC Independent Assessment Committee (IAC) reviewed Pfizer's application for AMC eligibility and deemed that the candidate vaccine was eligible for purchase pursuant to the terms and conditions of the AMC. This was communicated to the supplier with a copy to UNICEF on 23 August 2010. UNICEF Supply Division was thus able to start the procurement of PCV13 to GAVI-eligible countries (also see section 4.2).

2.4.3. Supply availability

Vaccine uptake in country is subject to both increases and decreases. A close monitoring of the supply and demand situation is required in order to ensure the sustainable supply to all countries upon introduction. This is especially important considering the uncertainties with regards to country requirements in the early years due to timing of actual introduction and uptake rates as well as long manufacturing lead-times of pneumococcal vaccines.

Since the time of signature of Supply Agreements in March 2010, GlaxoSmithKline and Pfizer have offered to increase the quantities originally made available for 2011-12 during the AMC Capacity Development Period[9]. Based on actual country requirements, such additional quantities may be accepted and Agreements amended accordingly. As of 31 March 2011, the contracted and offered supply for 2011-2013 are as follows (see Table 1):

Table 1. PCV contracted and offered supply

Year	2010	2011	2012	2013-2020	2021
Under Contract (in million of doses)	7.2	24.2	50	60	39
Offered Supply as of 31 March (in million of doses)	3.0 (actual)	46	54	60	39

Source: UNICEF Supply Division

As a result, the current available supply will be sufficient to support introduction and a sustainable supply of pneumococcal vaccines in the currently approved countries, although close management is required. It should also be noted that any increase in contracted supply to meet country demand may reduce the duration of the Supply Agreements.

2.5. Delivery of pneumococcal vaccines

2.5.1. GAVI-eligible countries approved for the introduction of PCV

To date, 19 countries have been approved for the introduction of pneumococcal vaccines with GAVI support. 13 countries were approved by the GAVI Board as of June 2009[10]. In addition, the EC approved the following countries during its meeting in August 2010: Benin, Burundi, Ethiopia, Madagascar, Malawi, and Pakistan. Five countries received a recommendation for conditional approval from the IRC and will be required to reply addressing the conditions during the May application round in order to receive a final recommendation for approval.

2.5.2. Coordination of introductions

In September 2010, GAVI set up the Pneumo Ad-hoc introduction group to ensure optimal coordination around the roll-out of PCV. The group is constituted by UNICEF, WHO, PATH and the GAVI Secretariat (see membership on Annex 3) to ensure day-to-day operational coordination and information sharing during the initial years of PCV introduction in GAVI-eligible countries. Under the Secretariat's leadership, the Pneumo Ad-hoc introduction group has proactively worked with countries to facilitate introduction of PCV.

Considering the immediate anticipated high demand for PCV and taking into account an anticipated constrained supply situation in the early years, an analysis was conducted to develop an interim procedure to allocate PCV vaccines between countries in case of limited supply and differences between available products and country product preferences. The goal of this procedure is to ensure a transparent, efficient allocation of PCV vaccines and products in case of insufficient supplies. The output of the procedure is a ranking of GAVI approved countries to inform the sequence in which countries will receive scarce PCV products. This procedure is available upon request[e].

2.5.3. Status of deliveries

The first shipment of AMC pneumococcal vaccines was delivered in Kenya in September 2010. As of 31 March 2011, UNICEF SD performed a total of 31 deliveries of PCV to nine countries. The overall number of doses delivered totalled 6.9 million.

Six of the 19 approved countries introduced PCV in this reporting period. Nicaragua was the first country to roll-out pneumococcal vaccines (in December 2010) followed by Guyana, Kenya, Sierra Leone, Yemen and Mali. An additional nine of the currently approved countries are expected to introduce PCV within the next four months and four late this year or early 2012 (see Annex 4).

2.5.4. The AVI Dashboard

In order to better monitor country readiness and required partner activities in support of new vaccines introductions, the Pneumo Ad-hoc introduction group developed and piloted a dashboard. The dashboard intends to provide a clear and concise view of the status of country readiness for vaccine introduction in each country and to help identify critical areas requiring partner attention or action to support introduction in country.

The dashboard is divided into three main sections to determine:

- The availability of financial resources – information provided by GAVI
- Supply considerations – information provided by UNICEF
- Countries 'readiness – information provided by WHO, GAVI and UNICEF

[e] Please contact: amc@gavialliance.org

Of note, countries' readiness is assessed through appraisal of logistics, social mobilisation and advocacy, training and human resources, and monitoring and evaluation capacity. The full list of items monitored is reported in Annex 5.

The dashboard was introduced in January 2011 and is updated on a weekly basis. A review to assess its usefulness and areas for improvement will be conducted by the Pneumo Ad-hoc introduction group by the end of 2011. This will also be the opportunity to review the indicators monitored through the dashboard and consider other items for inclusion such as the assessment of cold chain structure at regional and district levels in addition to national level.

2.6. Future perspectives

2.6.1. PCV vaccine pipeline

As part of the Accelerated Vaccine Initiative (AVI), GAVI monitors PCV vaccine pipeline to have a better knowledge of future market entrants. Table 2 provides an overview of current products in development based on publicly available information from industry, WHO and AVI assessments[11].

Table 2. PCV Vaccine Pipeline Overview

Vaccine & Manufacturer In development (most likely)	**Licensure Status**
China National Biotec Group	Development timelines information indicates earliest licensure in 2016
Intercell	
Fiocruz	
Merck	
Panacea Biotec Ltd.	
Sanofi Pasteur	
Serum Institute of India	
Shanta Biotech[12]	
Sinovac[13]	

Source: GAVI Secretariat

Provided that the products are successfully developed, these vaccines would need to be registered locally with a national regulatory authority (NRA). In order for the products to be considered for supply under the AMC, manufacturers would need to register as AMC Registered Manufacturers and would be required to submit a product summary file to WHO for prequalification review. Only applications from manufacturers located in a country with a NRA considered functional by WHO will be accepted for review. AMC Registered Manufacturers' offers in response to a Call for Offers will be considered by UNICEF and UNICEF may enter into a Provisional Supply Agreement (PSA) with those manufacturers whose product summary file has been accepted for prequalification review by WHO. If the product obtains WHO prequalification and is deemed AMC eligible by the IAC, the PSA would automatically turn into a Supply Agreement, entitling such manufacturer to initiate supplies and have access to the AMC Funds.

A number of initiatives are underway to help facilitate the development of additional market entrants:

- China National Biotec Group (CNBG), the leading vaccine manufacturer in China, and the US not-for-profit PATH are working in partnership to accelerate the development of an effective pneumococcal vaccine. This three-year project announced in 2009 will be implemented by Chengdu Institute of Biological Products (CDIBP), a subsidiary of CNBG based in Chengdu, Sichuan, with technical and financial support from PATH.

- GSK announced a partnership with Brazil's Oswaldo Cruz Foundation (Fiocruz), under which GSK will provide Fiocruz with access to the technology to its 10-valent pneumococcal conjugate vaccine. GSK will supply PCV10 to Fiocruz until the technology transfer is completed, allowing rapid incorporation of the vaccine into Brazil's national immunisation programme.

- The Bill & Melinda Gates also announced in March 2011 grants to Serum Institute of India to develop pneumococcal vaccines[14]. The Foundation will fund part of the cost for the clinical trials to facilitate the development of these vaccines.

2.6.2. Serotype replacement

In August 2010, a note reporting on the serotype replacement issue prepared by the IAC was published on the AMC website[15]. This note addresses questions raised around the extensive use of pneumococcal conjugate vaccine and if it will result in an increase of disease due to serotypes not covered in the vaccine (referred to as "serotype replacement") - there are over 90 serotypes of the pneumococcus bacterium - to the point where the benefit from the vaccine would significantly decrease.

In summary, the expectation of continued benefit from pneumococcal conjugate vaccine is based on the following:

- The most common paediatric serotypes responsible for pneumococcal disease now are the same as those identified 25 years ago;
- These core types causing pneumococcal disease are the most frequent serotypes in all regions.

Studies were conducted in developed countries (USA, Australia, Canada, and Europe) following the introduction of the 7 serotype vaccine (Pfizer's PCV7). These studies demonstrate a consistent decrease in the overall risk of invasive pneumococcal disease in the age group targeted for vaccination, reflecting a large decline in disease caused by vaccine serotypes and a relatively small or no increase in disease due to serotypes not in the vaccine.

The epidemiology in GAVI-eligible countries may be different from the one in developed countries. It is too early to say if the conclusions from the studies conducted in Western countries will apply to GAVI-eligible countries. WHO will continue to monitor this issue in the future years through further analysis on the impact of pneumococcal vaccines. The monitoring results will be presented to WHO's vaccine advisory group, SAGE, to assure that there is tight coupling of the analysis and process to policy formulation.

3. Second AMC

In October 2009, the Governments of five countries (the United Kingdom, Norway, the Netherlands, Canada, and Liberia) and the Millennium Foundation addressed a formal request to GAVI and the World Bank to jointly engage in exploratory work on a second AMC for vaccines. In response to this request, GAVI and the World Bank jointly developed a concept paper describing how to move forward.

However, while the potential value of an AMC was recognised by GAVI, the Executive Team decided in June 2010 to postpone initiation of work due to the funding challenge and uncertainty about GAVIs ability to fully fund demand for vaccine roll-out beyond existing commitments. In addition, the impact of the pneumococcal AMC and its cost effectiveness compared to other mechanisms had not yet been evaluated. Following GAVI's pledging conference in June 2011, the concept paper will be revisited by GAVI senior management.

4. AMC management structure

4.1. The AMC Secretariat

The AMC Secretariat is hosted by the GAVI Alliance and is responsible for providing operational, administrative and financial support to the pneumococcal AMC. This includes coordinating with the World Bank, UNICEF Supply Division and WHO, and liaising with AMC donors. The AMC Secretariat also manages the overall payment mechanism, in accordance with the terms of the AMC Supply Agreements, and implements GAVI's co-financing and default policy according to standard GAVI practice[f].

As the AMC is now in the implementation phase, the AMC Secretariat has been integrated with the Accelerated Vaccine Introduction (AVI) initiative which is responsible for coordinating the roll-out of all new vaccines. The GAVI Secretariat leads the AVI through a cross function management model, with team members from WHO, UNICEF, PATH and the Bill & Melinda Gates Foundation. The AMC Secretariat is therefore involved in all activities linked to the introduction of pneumococcal vaccines and leads the Pneumo Ad-Hoc introduction Group. Progress on AMC related activities is reported to the AVI management team on a weekly basis.

In addition, the AMC Secretariat organised the first AMC Stakeholders Meeting on 17 June 2010. As per the AMC legal agreements, the second AMC Stakeholders meeting will be organised in July 2011 – at the same time as the GAVI first Board Meeting of the year.

4.2. The AMC Independent Assessment Committee

The IAC serves a number of key functions. Most importantly, it has the mandate to review and approve the minimum technical requirements (TPP) that candidate products must meet to be eligible for AMC funding[g]. In addition, the IAC establishes when and if an adjustment of the pre-set long-term price of vaccines is necessary.

4.2.1. AMC Eligibility Determination Meetings

On 15 January 2010, Pfizer applied for AMC eligibility for PCV13 while GlaxoSmithKline submitted an application for PCV10 on 9 March 2010. Following WHO's confirmation of prequalification of each product, the AMC Secretariat organised two AMC Eligibility Determination meetings to review those applications.

PCV10 - 2 dose presentation

PCV10 in 2 dose presentation obtained WHO prequalification on 12 March 2010. The IAC met by teleconference on 16 April 2010 and unanimously determined that PCV10 meets all of the TPP criteria and that the candidate vaccine is therefore eligible for purchase pursuant to the terms and conditions of the AMC for pneumococcal disease[16]. The decision was communicated to the supplier on 6 May 2010.

PCV13, 1 dose presentation

PCV13 obtained WHO prequalification on 22 August 2010. The IAC met by teleconference on 23 August 2010 and unanimously determined that PCV13 meets all of the TPP criteria and that the

[f] Also see Section 3.1 on page 19 of the Pneumococcal AMC Annual Report 2010 http://vaccineamc.org/files/AMCannualReport10.pdf

[g] Also see section 3.2 on page 20 of Pneumococcal AMC Annual Report 2010 http://vaccineamc.org/files/AMCannualReport10.pdf

candidate vaccine is therefore eligible for purchase pursuant to the terms and conditions of the AMC for pneumococcal disease[17]. The decision was communicated to the supplier on 23 August 2010.

4.2.2. Renewal of memberships

As per Article 1 (b) of the IAC Bylaws, "IAC Members, including the Chairperson, are appointed by the IAC Selection and Oversight Panel. Subject to the other provisions of the IAC Charter and Bylaws, IAC Members, including the Chairperson, shall serve for an initial term of up to six years, subject to reappointment. Each IAC Member's term of appointment may only be renewed once". In addition, "Of the ten IAC Members initially appointed, the initial terms of three members shall expire at the end of three years, the initial terms of four members shall expire at the end of four years, and the initial terms of three members shall expire at the end of six years".

In May 2009, the AMC Secretariat requested that IAC members express their preferences with regards to the duration of their membership. Based on the feedback, the Secretariat established the duration of membership of each member[18].

Three IAC memberships came to an end on 31 December 2010. All members agreed to renew their membership.

The IAC membership remains therefore unchanged and comprises 11 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[19]. A list of IAC members can be found in Annex 6.

5. Monitoring and Evaluation Processes

5.1. AMC Baseline Study

Following the publication of the AMC Monitoring and Evaluability Study[20] in November 2008, the Secretariat commissioned the Swiss Centre for International Health (SCIH) in 2008 to conduct an AMC Baseline Study.

This study represented the first step in the monitoring and evaluation of the pneumococcal AMC. The goal of the study was to establish the environment prior to the AMC as a basis for future evaluations. The study identifies indicators related to the objectives of the AMC and populates them with baseline estimates which will determine the point of comparison for future Monitoring and Evaluation (M&E) activities. The study also models counterfactual scenarios to serve as a basis for ascertaining the potential impact of the AMC vis-à-vis traditional financial and procurement strategies.

The AMC Baseline Study developed a methodology to be used in future AMC M&E activities, including a list of defined indicators, a methodology for data collection at the country level and at the industry level. The study also defines the counterfactuals which will be used to evaluate the impact of the pilot. The report includes insights to help future M&E efforts in general and is linked to the availability and reliability of data collected. In particular, it notes the availability and difficulty of access for industry data.

The AMC Baseline Study was published on the AMC website on 10 December 2010[21].

5.2. Next steps on evaluation

A design and process evaluation of the pneumococcal AMC will be conducted in 2012. The purpose of this evaluation will be to evaluate how the implementation of the AMC fits the processes and timelines

established in the AMC legal agreements and will also assess the efficiency and effectiveness of the AMC design.

A first impact evaluation will then be conducted four years from the signature of the first Supply Agreements i.e. in 2014 – and be carried out every four years. It will focus on the achievements of AMC outcomes and assess causality between the AMC intervention and its results.

6. Media and Communications

2010 represented a pivotal year in the AMC's development and implementation with the celebration of the first introduction of AMC pneumococcal vaccines in GAVI countries. Communications activities were undertaken in partnership with the AMC donors, the World Bank, UNICEF and WHO. GAVI's communication objectives for the pneumococcal AMC were to:

- inform and educate target audiences about the AMC;
- increase the promotion of the AMC as an innovative market-based approach;
- mitigate criticism of the AMC in the press;
- celebrate the first introductions of pneumococcal vaccines in GAVI-eligible countries.

The following activities were employed to achieve the communication objectives:

6.1. Materials development

Existing communication materials were updated and re-designed in 2010 in order to provide a suite of materials tailored to the needs of various target audiences and also provide an ongoing means of managing communication with key AMC stakeholders. These materials are available both on the GAVI[22] and AMC websites[23] and in hard copy. They include:

- **"All in one" AMC Fact Sheet** provides: general information about the AMC funding mechanism; answers to the most commonly asked questions about AMCs; detailed information about the AMC process and the key stakeholders involved in the pilot; advice and guidance to developing countries seeking to accelerate access to new and affordable vaccines.
- **Global Pneumo Fact Sheet** provides**:** information about pneumococcal disease; the latest generation pneumococcal vaccines tailored to the needs of children in developing countries; explains the potential impact of pneumococcal vaccines if rolled out in more than 40 countries.
- **Pneumo Fact Sheet in Kenya** provides**:** information about pneumococcal disease and the burden of pneumonia in Kenya. It also introduces the potential of the pneumococcal vaccines reaching Kenyan children.

These publications are currently available in English, and will be available in French in 2011.

6.2. Media relations

Throughout 2010, GAVI's Media and Communications team has continued to work proactively on strengthening media relations with key reporters to promote AMC stories in key media outlets. During the period covered by this report, more than 100 articles featuring or citing the AMCs and/or the AMC pilot were published in English. Between June 2010 and March 2011, three specific events featured the AMC, namely World Pneumonia Day, the pneumococcal vaccine roll-out in Latin America, and the global roll-out of pneumococcal vaccines in Kenya.

Overall, the coverage was positive and relatively widespread. Criticism in outlets was systematically responded to.

6.3. Online communications

The pneumococcal AMC website was systematically maintained to reflect the progress made and to provide target audiences and stakeholders with direct access to key documents relating to the pneumococcal AMC. This site will be merged with the GAVI website in 2011 to increase visibility of the AMC.

6.4. Multimedia

To highlight the implementation phase of the pneumococcal AMC and celebrate that pneumococcal vaccines are now reaching children in developing countries in a sustainable manner, GAVI has developed two short films featuring the roll-out process of the pneumococcal vaccines. The following films are available on the GAVI website:

- First roll-out of pneumococcal vaccines in Managua, Nicaragua on 12 December 2010[24]
- Global roll-out of pneumococcal vaccines in Nairobi, Kenya on 14 February 2011[25].

6.5. Events

In order to strengthen the visibility of the AMC mechanism among target audiences, GAVI has participated in a wide range of conferences and events worldwide (See Table 3).

Table 3. AMC Key Events

Date	Event
13 April 2010	SAGE Meeting, Geneva, Switzerland,
21 April 2010	Geneva Health Forum, Geneva, Switzerland
21 June 2010	NUVI Meeting, Montreux, Switzerland
2 September 2010	Presentation to G20 Development Working Group sub-committee on applications of GAVI Innovative Finance mechanisms for development, Seoul, South Korea
21 September 2010	High-Level Side Event: Innovative Financing for the MDGs, UN Summit on the Millennium Development Goals, New York, USA
24 September 2010	2010 GAVI Focus Seminar at Norwegian School of Management Bi, Oslo, Norway
19 October 2010	2010 Innovative Health Financing Mini-Symposium “Do Innovative Financing Instruments Deliver More Money for Global Health?” Washington, DC, USA
9 November 2010	SAGE Meeting, Geneva, Switzerland,
18 November 2010	Global Symposium for Health Research, Montreux, Switzerland
16 December 2010	8th Plenary Meeting of the Leading Group on Innovative Financing for Development , Tokyo, Japan
20 January 2011	Innovative Finance Roundtable Discussion for GAVI Private Philanthropy, New York, USA

Source: GAVI Alliance Secretariat

GAVI has also partnered with countries and helped organise special events to mark and celebrate the roll-out of pneumococcal vaccines in developing countries. The roll-out of pneumococcal vaccines in the developing world is underway across three continents. As of 31 March 2011, Nicaragua, Guyana, Kenya, Sierra Leone, Yemen and Mali have introduced the vaccines in their routine immunization programmes

Between December 2010 and February 2011, GAVI has partnered with the introducing governments in the following events:

- **12th December 2010 - Managua, Nicaragua: First roll-out of pneumococcal vaccines in Latin America**
  International leaders in global health joined the Nicaraguan government and hundreds of parents and children to celebrate the roll-out of the pneumococcal conjugate vaccine in the developing world less than a year after it was introduced in high income countries.
- **29th January 2011 – Sana, Yemen**
  The Minister of Health Dr. Abdulkarim Rasae gave the symbolic "first shot" of pneumococcal vaccines to four month-old baby Rinad.
- **14th February – Nairobi, Kenya**
  Global roll-out of pneumococcal vaccines: Kenya's President Mwai Kibaki joined parents, health workers, ambassadors and donors in Nairobi to witness children being immunised as part of the government of Kenya's formal introduction of pneumococcal vaccine in its routine immunisation programme for all children.

7. Financial Activities

The financial structure of the AMC remains unchanged from the prior year. It is composed of the six AMC donors, the World Bank, GAVI, UNICEF, GAVI-eligible countries and eligible vaccine manufacturers[h].

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 grant 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 available amounts of AMC funds on a quarterly basis. To access the 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 and supply 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 GAVI funds and/or AMC funds, upon receipt of which GAVI transfers the requested funds into a designated procurement bank account held by GAVI. These funds once transferred can only be withdrawn by UNICEF. GAVI-eligible countries are obliged to co-finance the introduction of the pneumococcal vaccine, in accordance with GAVI's standard co-financing policy. Countries make their payments to meet their co-financing requirement directly to UNICEF.

[h] Refer to the Pneumococcal AMC Annual Report 2010 page 28-29 for the detailed description of the financial structure. http://vaccineamc.org/files/AMCannualReport10.pdf

7.1. 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 Figure 6). The six donors combined bring the total available AMC funds to US$ 1. 5 billion, funds that are dedicated solely to the procurement of the pneumococcal vaccine.

7.1.1. Donor contribution receipts

As of 31 March 2011, the World Bank received a total of US$ 395.9 million from AMC donors (see Table 4).

Table 4. Contribution receipts from AMC donors, as of March 31, 2011 (in US$ millions)[i]

Donors	Grant Amount	Cumulative receipts	Remaining Contributions Receivable
Fixed Schedule Donor Contributions			
Italy	635.00	210.64	424.36
Russia	80.00	16.00	64.00
Gates Foundation	50.00	20.00	30.00
Subtotal	765.00	246.64	518.36
On-Demand Donor Contributions			
Norway	50.00	2.08	47.92
Canada	200.00	125.07	74.93
UK	485.00	22.20	462.80
Subtotal	735.00	149.35	585.65
Total	**1,500.00**	**395.99**	**1,104.01**

Source: The World Bank

7.1.2. Reporting on investment activity and results

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. The World Bank also provides standard financial management and administrative services with respect to donor contributions, AMC commitments and disbursements.

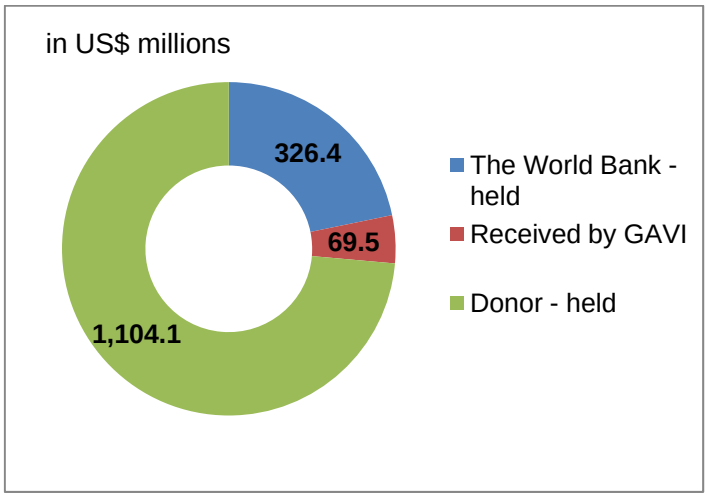
7.2. AMC donor funds: inflow to GAVI

As of 31 March 2011, the World Bank has disbursed US$ 69.5 million to GAVI of which US$ 63.5 million was received from 1 April 2010 – 31 March 2011. This leaves a balance of US$ 326.4 million

[i] Italy contribution payments in EUR have been hedged into USD. Italy payment received on February 28, 2011 will be converted in US$ on June 30, 2011 at the swap maturity date. The amount reflected in the table represents the US$ amount to be received from swap counterparts.
Canada's contribution (the "initial funds") in the amount of US$ 105.3 million is not available for AMC subsidy disbursement until annual maximum cumulative contributions ("subsequent funds") as provided in Canada's Grant Agreement have been disbursed.

held by the World Bank, of which US$ 221.1 million is available for immediate disbursement to GAVI (see Figure 7).

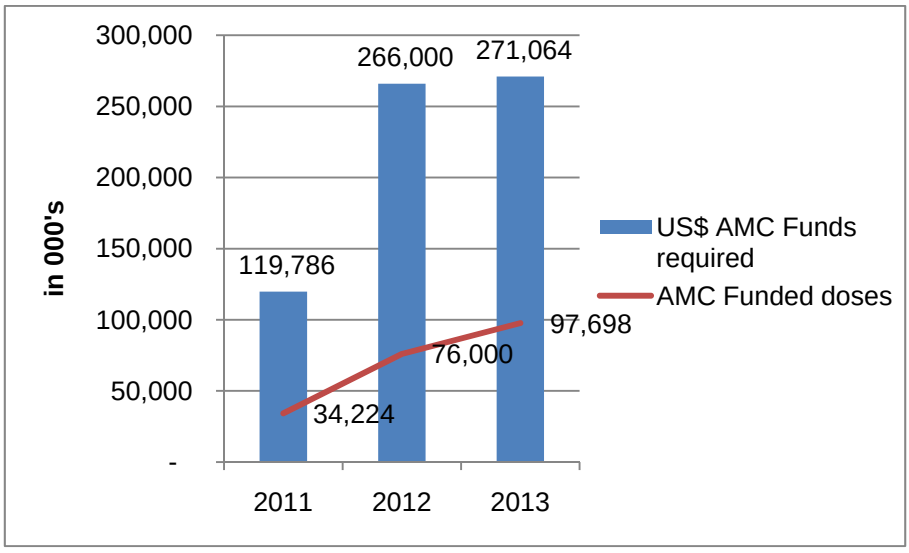
Figure 7. Status of AMC donor funds, as of 31 March 2010 (in US$ millions)



Source: GAVI Alliance Secretariat

As part of the reporting process, GAVI submitted two Semi-Annual Estimates to the World Bank during the reporting period (September 2010, March 2011). According to the most recent (March 2011), it is anticipated that US$ 656.9 million of AMC funds will be needed to procure 207.9 million doses of the pneumococcal vaccine from January 1, 2011 – December 31, 2013. This translates to a projected weighted average vaccine price of US$ 6.76 per dose over the three year period, which covers doses with AMC top-up and without. Fulfilment costs are estimated at US$ 0.19 per dose[j]. These weighted average prices are based on the most up-to-date dosage demand and financial cost forecast available (see Figure 8).

Figure 8. Upcoming 36 months forecast, as of March 31, 2011



Source: GAVI Alliance Secretariat

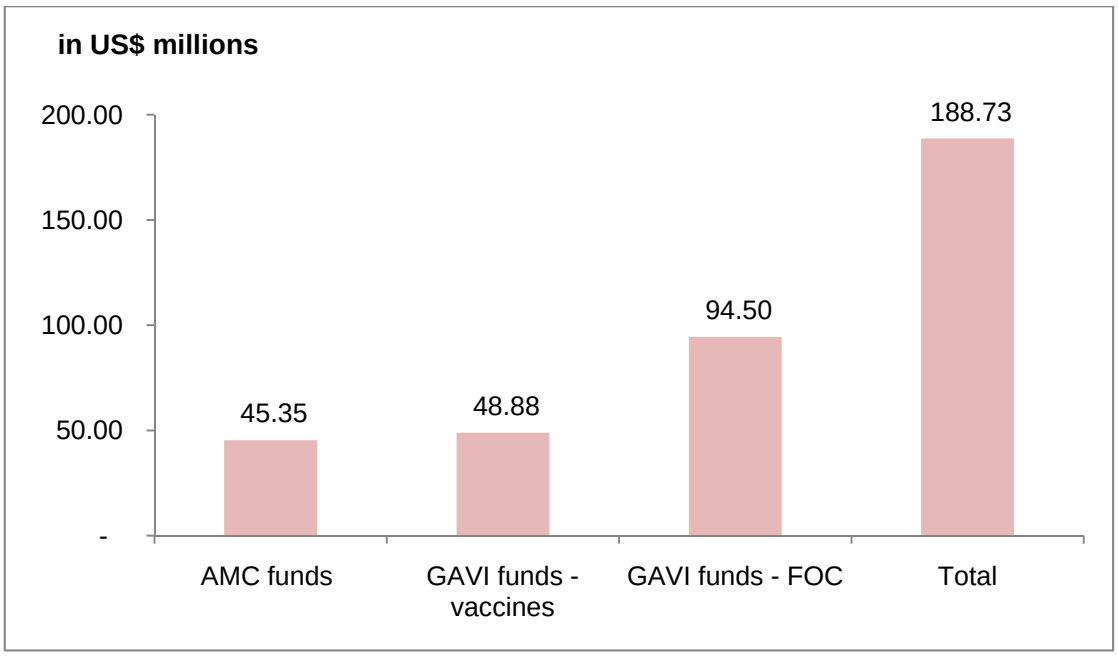
[j] Fulfilment costs are the extra costs incurred in supplying vaccines, in addition to the cost of the vaccine itself. These costs typically include the cost of syringes, safety boxes and freight.

7.3. UNICEF procurement: outflow of AMC donor funds

From 1 April 2010 to 31 March 2011, GAVI has disbursed US$ 94.2 million to UNICEF for the purchase of 12.96 million doses of pneumococcal vaccines. Of the US$ 94.2 million, US$ 45.4 million were from AMC funds.

In the prior reporting period, GAVI had initially transferred $189 million to the UNICEF procurement bank account. The $189 million represented both the AMC-funded and GAVI-funded portion of the minimum purchase obligation of the two signed supply agreements, also known as the Firm Order Commitment (FOC). Subsequently on 11 May 2010, GAVI, UNICEF and the World Bank reached an agreement and entered into two promissory notes, one for each signed supply agreement, to cover the AMC-funded portion of the FOC. As a result, the $94.5 million AMC funded portion was returned to GAVI and the remaining $94.5 million represents the GAVI-funded portion only. This balance of $94.5M will be drawn down starting in the fourth quarter of 2011. Concurrently, the World Bank will transfer directly into the UNICEF procurement bank account the AMC-funded portion of the FOC one quarter prior to years 1, 2 and 3 of each supply agreement

Figure 9. Total cash disbursements to UNICEF's procurement account, as of 31 March 2011



Source: GAVI Alliance Secretariat

As of 31 March 2011, 19 countries had been approved by the GAVI Board to receive financial support for the procurement of pneumococcal vaccine for the 2011 programmatic year. This approved financial support amounts to US$ 416.6 million and translates into the procurement of approximately 56.5 million doses of the pneumococcal vaccine. The co-financing level for these 19 countries ranges from US$ 0.15 to 0.35 per dose.

8. Challenges and Future Priorities

8.1. Resource mobilisation

The GAVI Alliance has the opportunity to deliver new life-saving vaccines against the world's biggest childhood killers while, at the same time, further expand global immunisation coverage. If fully funded, over the next five years, support from the GAVI Alliance will help immunise 243 million children in 72 countries, including 230 million with pentavalent vaccines; 90 million with pneumococcal vaccines; and 53 million with rotavirus vaccines, while simultaneously strengthening routine immunisation at large.

A GAVI pledging conference entitled "Saving children's lives" will be held on 13 June 2011 in London to seize this opportunity to radically reduce child mortality by 2015 and beyond by introducing new vaccines in the poorest countries.

Participants at the conference, including governments and donors, implementing countries, the vaccine industry, UN partners and the private sector, will pledge to meet the US $3.7 billion challenge. Out of this US $3.7 billion, approximately US $1 billion will be required for the roll out of pneumococcal vaccine.

The June pledging conference will seek to fully fund country demand up to 2015 and beyond through a three-fold approach engaging a wide range of GAVI stakeholders: increased levels of donor contributions and innovative finance commitments; new perspectives on co-financing, and reduction in vaccine prices.

8.2. Meeting country demand

In the context of the AMC, UNICEF Supply Division (SD) enters into supply agreements with manufacturers who commit to supply PCV for a period of 10 years, with a starting date up to five years into the future. The actual procurement of PCV under those contracts depends on demand from GAVI countries. The AMC only guarantees to manufacturers a purchase corresponding to 45% of one year of the annual contracted quantity. However it is important to keep in mind that contracted companies are legally bound to supply the awarded doses and must thus build up production capacity to be able to meet their contractual obligations. Therefore, in order to ensure best possible utilisation of AMC funding in line with GAVI's Supply and Procurement Strategy to be presented to the GAVI Board in July 2011, the objective of market shaping and ensuring adequate supply to meet demand, GAVI will need to optimise utilisation of available capacity.

The current PCV supply available is sufficient to meet demand from the 19 approved countries. A new call for supply offers will be issued on 8 April 2011 with the objective to contract additional supply for new country applications likely to be approved in 2011 and beyond. It is estimated that an additional 74 million doses (SDF v3.0) will be required from 2016 to fully meet GAVI country demand.

New supply agreements are expected to be signed in September 2011.

8.3. Sustainability

The grandfathering of the AMC approved by the GAVI Board in June 2010 will allow those countries who were eligible at the time of signature of the AMC Legal Agreements (2009) to have access through UNICEF to pneumococcal vaccines under the AMC Terms and Conditions. This means that graduated countries will be able to purchase pneumococcal vaccines at the contracted tail prices and suppliers will receive the AMC top-up price. However, these countries will need to fully fund the AMC tail price for all doses. Similarly, GAVI "graduating countries" (see section 2.1) will also need to fully fund the AMC tail price after five years of support.

As the success of the pneumococcal AMC relies on country demand, the willingness of those countries to adopt and finance the cost of vaccines will have an impact on the ability of the project to achieve its objectives.

To help mitigate this risk, as part of GAVI's business plan and strategy, GAVI and partners are working with those countries graduating from GAVI support to help them develop strategies to fund the vaccines after GAVI support has ended.

8.4. Exploiting the full potential of the AMC

The pneumococcal AMC was designed to fund the establishment of an estimated annual requirement upon full uptake in countries of approximately 200 million doses. However, the changes to eligibility and hence the need for some countries to in a short period of time fully fund the AMC tail price and the requirement that countries reach 70% coverage rate makes that target demand more difficult to reach. Most importantly, the major "uncertainty" regarding whether or not the full potential of the pneumococcal AMC will be exploited by 2021 is whether or not large countries, such as India and Nigeria, which represents more than 30% of total demand, will adopt pneumococcal vaccines.

In response to this and other issues, a large country task team has been set up by the Programme and Policy committee of the Board to review how GAVI can best support these countries in their decision making about new vaccines. A report from this committee will be provided to the GAVI Board in December 2011.

8.5. Coordination of pneumococcal vaccine introduction

In addition to the 19 approved countries for PCV, if financing is available (see section 8.1), GAVI estimates that another 35 countries will introduce pneumococcal vaccines by 2015. Of these, 30 countries are expected to introduce between 2012 and 2013. In addition to the challenge linked to ensuring availability of PCV supply, the large numbers of countries expected to apply for PCV in the next few years will require close coordination and strong country support from WHO, UNICEF and other partners. Ensuring that appropriate preparatory activities are conducted in countries will be essential to support the continued extensive introduction of PCV in the coming years.

9. Conclusion

When the first pneumococcal AMC Annual Report was published in May 2010, UNICEF had recently entered into provisional supply agreements with two suppliers, showing a positive response from industry to the pneumococcal AMC. Within the past year, two vaccines received determination of AMC Eligibility and are now being introduced in GAVI-eligible countries. Availability of additional supply in the early years ("head room") has made it possible to meet demand from countries.

Thanks to the AMC, new pneumococcal vaccines are now being provided to the poorest countries within a year of those vaccines being available in high income countries. Six countries have already introduced pneumococcal vaccines and another 13 countries will be rolling out this new vaccine in the coming months. This will allow for more than three million children to be vaccinated against pneumococcal disease by the end of 2011.

The tail price of pneumococcal vaccines under the AMC will be a key factor in the decision of graduating and graduated countries to introduce this new vaccine in spite of GAVI's support ending. The entrance of new manufacturers on the market is expected to lead to a further decrease in prices.

The success of the AMC also relies on two other main factors - the first of which is country readiness to introduce. With the unprecedented availability of new life saving vaccines, countries will need to ensure the appropriate systems are strengthened to enable roll-out. Paramount is adequate cold chain capacity and sufficient human resources.

The second key factor to the success of the pneumococcal AMC is GAVI's ability to finance the procurement. To this end, GAVI must successfully meet its funding challenge for 2011-2015.

If fully funded, pneumococcal vaccines could be introduced in more than 40 countries by 2015 and save approximately 900,000 lives by 2015 and up to seven million lives by 2030.

Annexes

1. List of modifications to the AMC legal agreements

AMC Offer Agreement

Provision: Condition 4.3, AMC Terms and Conditions
Amendment: "Once a Determination has been made by the IAC about an Application for AMC Eligibility, the AMC Secretariat shall publish the IAC's determination on the AMC website".

Provision: Condition 5.1, AMC Terms and Conditions
Amendment: "The GAVI Alliance shall publish the GAVI Strategic Demand Forecast on the AMC Website annually and as soon as the necessary information is available from the last procurement cycle and relevant GAVI Board meeting".

Provision: Condition 5.2, AMC Terms and Conditions
Amendment: "In support of achieving the AMC Objectives, a Call for Supply Offers may be issued once per calendar year or more or less frequently if so decided by the GAVI Alliance in consultation with UNICEF. A written explanation of the decision to issue or not to issue a Call for Supply Offers based on such consultation will be provided to all parties of the AMC Stakeholders Agreement."

Provision: Pro Forma Supply Agreement
Amendment: "This Agreement will become effective upon signing by both Parties".

AMC Procedures Memorandum

Provision: Section 2.1
Amendment: "(iv) Estimated timeline for submitting a Product Summary File to WHO".

Provision: Section 3.2.3
Amendment: "The Product Summary File submitted to WHO *and* a copy of written confirmation from WHO to the manufacturer that the Product Summary File has been accepted for review".

Provision: Section 3.3.2
Amendment: "As soon as possible after the receipt of the completed Application for AMC Eligibility….."

Provision: Section 3.3.3.
Amendment: "Subject to the requirements of the IAC Charter and Bylaws, the AMC Secretariat shall schedule an AMC Eligibility Determination Meeting as soon as reasonably possible after receipt by the AMC Secretariat of an Application for AMC Eligibility in respect of which the relevant candidate vaccine has met WHO Prequalification".
Provision: Section 4.3.1(i)
Amendment: "For vaccines that are not AMC-Eligible Vaccines, if available, a copy of written confirmation from WHO that the Product Summary File has been accepted for review by WHO….."

Provision: Section 4.5.1
Amendment: "… UNICEF shall use its reasonable efforts to reach an agreement in principle to a Supply Agreement with a manufacturer within 20 IBRD Business Days from receipt by the manufacturer of notification of the Supply Commitment Quantities being awarded to such manufacturer. A manufacturer shall communicate its acceptance of the proposed award in a formal

letter to UNICEF which constitutes an agreement in principle.
….. Thereafter, UNICEF shall use its reasonable efforts to enter into a Supply Agreement within 30 IBRD Business Days from reaching an agreement in principle…".

IAC Charter and Bylaws

Provision: Article V(a), IAC Charter
Amendment: "The IAC shall determine in its sole discretion whether any vaccine submitted by an AMC Registered Manufacturer in an Application for AMC Eligibility meets or exceeds the relevant TPP requirements."

Provision: Article III(b) of the IAC Bylaws:
Amendment: "As soon as reasonably possible after receipt of such Application for AMC Eligibility, the Chairperson shall call and AMC Eligibility Meeting and shall review and consider such application in accordance with these IAC Charter and Bylaws."

Provision: New Provision, IAC Charter and Bylaws Article V (b) (iii)
Amendment: "IAC Members may require manufacturers to provide additional information for the purpose of assessing AMC eligibility. In such cases, IAC Members shall contact the IAC Chairperson or Vice Chairperson and inform them of the additional information required. He or she shall copy all IAC Members as well as the AMC Secretariat in any such correspondence. The IAC Chairperson or Vice Chairperson will review the request for information and if approved will request that the AMC Secretariat liaise with the applicable manufacturer. She or he shall make herself or himself available for any necessary meeting or conference call with such manufacturer. The AMC Secretariat will also attend any meeting or conference call between the IAC and an AMC Registered Manufacturer in order to record minutes of the discussion. The AMC Secretariat will prepare minutes of any such meetings for review within five business days. IAC Members shall review and approve such minutes within ten business days after receipt. The minutes may be published on the applicable AMC Website to the extent that the information contained in such minutes does not at any time include any Confidential Information".

2. GAVI-eligible countries as of 31 March 2011

56 countries are currently eligible for GAVI support based on a Gross National Income (GNI) per capita below or equal to US$1,500:

- Afghanistan
- Bangladesh
- Benin
- Bolivia
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Central African Republic
- Chad
- Comoros
- Congo, Dem Republic of
- Côte d'Ivoire
- Djibouti
- Eritrea
- Ethiopia
- Gambia
- Ghana
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- India
- Kenya
- Korea, DPR
- Kyrgyz Republic
- Lao PDR
- Lesotho
- Liberia
- Madagascar
- Malawi
- Mali
- Mauritania
- Mozambique
- Myanmar
- Nepal
- Nicaragua
- Niger
- Nigeria
- Pakistan
- Papua New Guinea
- Rwanda
- São Tomé e Príncipe
- Senegal
- Sierra Leone
- Solomon Islands
- Somalia
- Sudan
- Tajikistan
- Tanzania
- Togo
- Uganda
- Uzbekistan
- Viet Nam
- Yemen
- Zambia
- Zimbabwe

Graduating countries

As a result of the revised eligibility criteria, 16 countries are graduating from GAVI support in 2011 because their GNI per capita exceeds the new eligibility threshold of US$ 1,500.

Exceptionally, these countries have a final opportunity in 2011 to apply for GAVI support for the introduction of new and underused vaccines.

In addition, the graduating countries listed below will be able to apply for pneumococcal vaccines after 2011 under the AMC Terms and Conditions provided that they fully self finance the vaccine.

- Angola
- Armenia
- Azerbaijan
- Bhutan
- Bolivia
- Congo Rep.
- Cuba
- Georgia
- Honduras
- Indonesia
- Kiribati
- Moldova
- Mongolia
- Sri Lanka
- Timor-Leste
- Ukraine

3. Composition of the Pneumo Ad-hoc introduction group

Organisation	Team members
GAVI Alliance	**Santiago Cornejo**, Senior Programme Manager, Country Finance, Programme Delivery **Johanna Fihman**, Senior Programme Assistant, AMC, Policy and Performance
PATH	**Lauren Franzel**, Vaccine Market Analyst, Strategic Vaccine Supply
UNICEF PD	**Osman Mansoor**, Senior Advisor EPI (New Vaccines)
UNICEF SD	**Ann Ottosen**, Contracts Manager **Yalda Momeni**, Contracts Officer
WHO	**Hemanthi Dassanayake-Nicolas,** Technical Officer, New and Underutilized Vaccines **Carsten Mantel,** Medical Officer, Group Leader for the New and Underutilized Vaccines **Gill Mayers,** Technical Officer, New and Underutilized Vaccines

Source: GAVI Secretariat

4. Pneumococcal vaccines introductions as of 31 March 2011

Country	Product	Year	Month
Nicaragua	PCV13	2010	December
Guyana	PCV13	2011	January
Kenya	PCV10	2011	January
Sierra Leone	PCV13	2011	January
Yemen	PCV13	2011	January
Mali	PCV13	2011	March
Congo, DR	PCV13	2011	April
Honduras	PCV13	2011	April
Central African Republic	PCV13	2011	June
Gambia	PCV13	2011	June (switch from donation)
Rwanda	PCV13	2011	June (switch from donation)
Benin	PCV13	2011	June/July
Cameroon	PCV13	2011	July
Burundi	PCV13	2011	July
Ethiopia	PCV10	2011	July
Malawi	PCV13	2011	October
Congo, Rep.	PCV13	2012	January
Pakistan	PCV10	Under consideration	Under consideration
Madagascar	PCV10	Under consideration	Under consideration

Source: GAVI Secretariat

5. AVI Dashboard indicators and means of validation

Item	Source of Information	Means of validation
Availability of Financial Resources		
GAVI grant is sufficient to cover country's introduction	GAVI	*Confirmation from GAVI*
Vaccine co-pay terms met for all previously introduced vaccines	GAVI	*No default on co-financing*
Supply Considerations		
Vaccines available for allocation	UNICEF SD	*Communication/confirmation from SD*
Purchase Order confirmed	UNICEF SD	*Communication/confirmation from SD*
Confirm country-level approval, regulatory, or registration requirements met	UNICEF SD	*Communication/confirmation from SD*
Country Preparedness - Program Readiness		
Decision Letter with approved doses sent to country	GAVI	*Confirmation from GAVI*
Confirmation of projected introduction date	UNICEF SD	*Communication/confirmation from UNICEF or GAVI*
cMYP valid for at least 1 year from time of introduction	GAVI	*Confirmation from GAVI*
Logistics	WHO/UNICEF PD	*Input from UNICEF PD or WHO HQ and/or country office*
Cold chain infrastructure has sufficient capacity at central and regional levels	WHO	*Input from WHO HQ and/or country office*
Status of in-country transport (air, surface, other as required)	WHO	*Input from WHO HQ and/or country office*
EVM conducted within 2 years of introduction	WHO	*Confirmation from WHO*

Status of activities as identified in EVM Improvement plan	WHO	*Input from WHO HQ and/or country office*
Sufficient Waste Management capacity	WHO	*Input from WHO HQ and/or country office*
Documentation for vaccine record keeping (Vaccine record keeping, child immunization cards, Tally sheets and Reporting registers)	WHO	*Input from WHO HQ and/or country office*
Inventory management	WHO	*Input from WHO HQ and/or country office*
Social Mobilization & Advocacy	WHO	*Input from UNICEF PD or WHO HQ and/or country office*
Training & Human resource Availability	WHO	*Input from WHO HQ and/or country office*
Monitoring & Evaluation Capacity	WHO	*Input from WHO HQ and/or country office*
Surveillance	WHO	*Input from WHO HQ and/or country office*
AEFI reporting	WHO	*Input from WHO HQ and/or country office*
Sentinel	WHO	*Input from WHO HQ and/or country office*
Programmatic monitoring	WHO	*Input from WHO HQ and/or country office*

Source: GAVI Secretariat

6. IAC membership

Robin Biellik
Retired from PATH, consultant for WHO, Switzerland

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
Head, Public Private Partnership, 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, Center for Child Health Care Studies, Harvard Medical School, USA

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

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