CONSULTATION & ADVISORY PROCESS
ADVANCE MARKET COMMITMENT FOR PNEUMOCOCCAL VACCINES

Following a proposal by Italy, in January 2007 five nations (Italy, the United Kingdom, Canada, Russia, Norway) and the Bill & Melinda Gates Foundation committed US$1.5 billion to launch a pilot Advance Market Commitment (AMC) that would help speed the development and availability of a new vaccine which is expected to save the lives of 5.8 million children by 2030. The AMC pilot represents the first step in a historic effort to create a market for life-saving vaccines for children in the world's poorest countries. The new initiative will target pneumococcal disease, a major cause of pneumonia and meningitis that kills 800,000 children under five every year. An Advance Market Commitment is an innovative concept with the potential to save millions of lives by accelerating access to vaccines that would not otherwise be available for many years.

From 2005 to present, the World Bank, The GAVI Alliance and the AMC Donor Committee sought stakeholder input on the planning and design of the pilot AMC through expert groups, consultations, meetings and roundtables. The aim was to incorporate into the design of the AMC the recommendations of economists, global health experts, medical practitioners and scientists from developing and industrialized countries as well as manufacturers and civil society organizations. This document outlines the process to date.

SECTION 1: AMC WORKING GROUPS AND EXPERT COMMITTEES

Disease Expert Committee, February 2006:
Following Italy's presentation of the idea of AMC in February 2005, the G7 Ministers of Finance, in December, endorsed the "Tremonti Report," which presented the economic and health rationale for implementing an AMC for six vaccines on diseases mainly affecting poor countries. The G7 Ministers of Finance decided to go ahead with a pilot AMC and requested the World Bank and GAVI to convene experts and perform necessary analytical work required to develop a proposal for their consideration in April 2006. An independent Disease Expert Committee, chaired by Dr. Ntaba, the Minister of Health of Malawi, and comprising developing and industrial country experts in public health, epidemiology, industry economics, vaccine development and law was convened to assess the key question of which of the six vaccines included in the "Tremonti Report" would be most suitable for a pilot AMC. The meeting was held February 27- 28 in Paris. After careful evaluation of available data, the committee made the following recommendations:

1) Vaccines against all six candidate diseases (HIV/AIDS, human papilloma virus, malaria, pneumococcus, rotavirus and TB) are public health priorities.

2) Pneumococcal vaccines are the most suitable candidate for a demonstration/pilot AMC because of their ability to demonstrate quickly that the AMC concept works and because of their potential impact on the health of the target populations.

3) A second demonstration AMC is recommended to test its impact on early-stage vaccines. Given the early and uncertain state of the science for HIV/AIDS vaccines, an AMC would have greater impact on this vaccine once the AMC concept had been successfully piloted and the candidate pipeline was more advanced. While both malaria and TB vaccines would be suitable candidates for a demonstration AMC, a malaria vaccine with 80% or greater efficacy against severe disease would be the best candidate for a demonstration AMC.

4) A number of additional factors are important to the success of an AMC pilot. These include mitigating demand risk and coordinating the AMC pull with direct push funding.

<u>AMC for Pneumococcal Disease:</u> The minimum size of an AMC for pneumococcal vaccines is estimated at $1.5 billion in nominal terms ($828 million in 2006 dollars). These resources would be disbursed as AMC payments over a period of 9 years.

Additional discussions with donors would be needed to determine the optimal structure for AMC payments. An AMC for pneumococcal would be expected to motivate suppliers to invest in production capacity to supply poorest countries, resurrect 'discontinued' vaccine development programs, and develop second-generation technologies (e.g., protein vaccines) with increased focus on developing countries.

For additional information on the Disease Expert Committee including membership and the complete report, please refer to addendum one.

AMC Advisory Group:
An AMC Advisory Group was established in January 2006 to help drive and streamline the process. For group membership please refer to addendum two. The group held several meetings during the course of 2006:

February 14-15, 2006:
The group held its inaugural meeting over a two day period in Washington DC. Primary issues discussed at the meeting included the AMC work plan and overview of key inputs for the G7 paper; IAC, structure, policies, and tail pricing; criteria to be used for selecting the various expert committees; and AMC implementation functions.

March 7, 2006
Primary agenda items discussed at the meeting included the Expert Committee's prioritized list of vaccines for the AMC pilot; inputs to the draft pilot proposal and a discussion of IAC issues.

March 2006:
The Advisory Group held a virtual meeting in March 2006 to discuss and comment on the pilot proposal draft before sending it to G7 Deputies for review.

April - May 2006:
Issues discussed during these meetings focused on advance preparations for the upcoming G7 and G8 meetings, such as communications outreach and discussions among broader global health community; post G8 outreach and next steps; and donor outreach strategy.

For additional information on the AMC Advisory Group terms of reference (TOR) and AMC pilot proposals please see addendum two.

Technical Working Group, September & November 2006:
The Technical Working Group on Advance Market Commitments was established to review the technical, institutional and financial aspects of a pilot AMC for a pneumococcal vaccine. The group held two meetings during 2006.

September 7, 2006:
In order to build on the support expressed for AMCs at the G8 Heads Summit in St Petersburg, Russia, in July 2006, the Finance Ministers of Italy, the UK and Canada jointly convened the first Technical Working Group in Rome. Attendees reviewed the work undertaken thus far on the legal, technical, institutional and financial aspects of an AMC pilot and agreed that additional technical work would be necessary.

November 9, 2006:
The Technical Working Group held its second meeting in London. The UK Treasury hosted the meeting. Attendees reviewed the technical, institutional and financial aspects of a pilot Advance Market Commitment for a Pneumococcal vaccine. The group considered the technical work on the pilot AMC to be significantly advanced and agreed that the critical challenge going forward would be to secure financial commitments necessary for a launch. A number of donors reiterated their commitment to launching a pilot early in 2007 and encouraged others to consider joining them.

Representatives from 15 countries, including Australia, Brazil, Canada, China, France, Italy, Japan, Netherlands, Norway, Russia, Spain, Sweden, Switzerland, United Kingdom and the United States attended both meetings. Representatives from the European Commission, the World Bank, (GAVI), the Gates Foundation, the WHO, and industry also participated in these meetings.

Launch of the Pilot Project: February 2007
On 9th February 2007 the AMC pilot project was formally launched in Rome with the official pledge of US $ 1,5 billion (Italy with a contribution of US $ 635 million, UK 485, Canada 200, Russia 80, Norway and Bill & Melinda Gates Foundation 50 each). Her Majesty Queen Rania Al-Abdullah of Jordan, the President of the World Bank, the Finance Ministers of the three major donors, as well as high-level representatives of the other donors and the international health community attended the ceremony, which provided the opportunity to inform the general public about both the tragic disease burden of pneumococcus and the innovative features of AMC.

Donor Committee (DC): March 2007 – May 2008
The DC has been established with the task of steering the stakeholders activities necessary to ensure the full legal and economic implementation of the AMC. Tasks of the DC include: managing overall progress towards the finalization of the AMC Framework Agreement; developing the AMC governance structure and the strategies for consultation with other stakeholders; developing and approving legal text for signature by donors; promoting the understanding of the AMC within the broader donor community and with other stakeholders. Five meetings were held so far: March 2007, in Rome, May in Ottawa, November in Seattle, January 2008, in Washington, March in Rome, May in Ottawa.

Target Product Profile (TPP) Expert Committee on Pneumococcal Vaccine: April-September 2007, December 2007, March 2008
Upon request of the Donor Committee (DC), the World Health Organization (WHO) set up an ad-hoc TPP Expert Committee to facilitated the establishment of the Target Product Profile (TPP). The TPP specifies the minimum quality, safety and immunogencity needed for the AMC vaccines for Pneumococcal disease. The TPP is a scientific specification a vaccine must meet in order to qualify for AMC funding. Members of the committee were selected based on technical expertise in the areas of epidemiology, pneumococcal disease, public health, vaccine formulation, design and delivery, and health economics as well as appropriate geographical representation. The committee held its only meeting in Sep 2007 and sought feedback on the draft TPP from stakeholders belonging to industry, government and civil society. The committee submitted the final TPP to the AMC's Independent Assessment Committee (IAC) for approval, expected in spring 2008.

For additional information on the technical profile of committee experts and the stakeholders consulted in the TPP process, please refer to addendum three.

Economic Expert Group, August 2007 – April 2008:
The Economic Expert Group was convened to provide recommendations on AMC design to the Donor Committee, GAVI and the World Bank. The design issues being considered by the Economic Expert Group include the price per dose for the AMC vaccine, the relationship between the country co-payment and the tail price, supply obligations in the post-AMC period, the ability and willingness of developing countries to pay, and a review of currency issues. The Economic Expert Group was also tasked to provide advice on issues not directly relevant to the AMC Framework Agreement but nevertheless

important to the success of the AMC, such as demand-related issues and evaluation indicators most appropriate for assessing the pilot AMC.

The Economic Expert Group published its report on 1 April 2008. The report can be found at www.vaccineamc.org

For Economic Expert Group membership and TOR please refer to addendum four.

Implementation Working Group, April 2008 – May 2008

On March 10, 2008, the AMC Donor Committee discussed the Economic Expert Group's Report and agreed with its conclusion that modifications to the AMC structure could enhance the prospects of achieving AMC's objectives. Donors agreed to commission further work to recommend specific terms and parameters for an enhanced structure. Consequently, Donors have decided to create an Implementation Working Group (IWG) with the task of recommending a specific proposal for the AMC structure and parameters, inclusive of the implementation features noted above. Donors expect the proposal, due May 2008, to be detailed and operational so as to allow donors to finalize the detailed terms and features of the binding offer to be presented to industry in the legal documentation.

For Implementation Working Group membership and terms of reference please refer to addendum five.

SECTION 2: DEVELOPING COUNTRY OUTREACH

DEVELOPING COUNTRY CONSULTATIONS (SPRING, 2006)

As part of the background work undertaken by GAVI and the World Bank on the development of a pilot AMC for Vaccines, initial consultation and/or presentation of the AMC concept was conducted with key developing country regional institutions. These included the African Union and its New Partnership for Africa's Development (NEPAD) program, the Pan American Health Organization (PAHO), and the Association of Southeast Asian Nations (ASEAN). The meetings aimed to provide these organizations with an opportunity to comment on the AMC concept and issues critical to developing countries.

Primary topics of discussion at these meetings included:

- **Fit with existing policy frameworks**: Both PAHO and AU/NEPAD signalled that the AMC concept fits well into existing regional policy frameworks. Tackling the market failure that has led to the under-production of vaccines and drugs for diseases of poverty was included as an African priority in the AU/NEPAD Health Strategy Initial Programme of Action.

- **Need for functioning delivery systems:** Donors will need to signal a commitment to ensuring the predictable finance required for strengthening health systems in the poorest countries. Adequate delivery systems for pilot and other AMC-accelerated vaccines are crucial to ensuring that target populations will be reached.

- **Leveraging developing country support:** An important way of reducing risk and increasing the likelihood of African countries choosing to buy the vaccines is to involve African stakeholders and public health experts in particular in AMC design and administrative processes, and to build on existing institutional arrangements where Africa has a meaningful voice.

- **Subsidy and Co-payment price-setting:** If the AMC is truly a modified market, the subsidy price will be influenced by the scale of actual demand, which will not be known for several years in many cases. In terms of setting a co-payment price, this will also depend on actual demand. Moreover, levels of co-payment will need to reflect ability to pay in the real world.

Child Pneumonia Prevention – Africa Regional Advocacy Workshop, Tanzania October 23-25, 2007

The workshop aimed to draw together leading public health professionals committed to advancing child health and survival initiatives in their respective countries. Prominent child health experts from nine African countries, namely: Kenya, Uganda, Malawi, Zimbabwe, Democratic Republic of Congo, Burundi, Nigeria, Ethiopia and Tanzania were represented.

Workshop participants shared best practices related to childhood pneumonia prevention and discussed how effective advocacy efforts can influence change at the policy level. Major issues covered during the three-day workshop included conducting advocacy for child pneumonia prevention, identifying audiences and customizing messages, forging strategic partnerships and coalitions, identifying opportunities to impact change, and developing winning action plans.

Global Immunization Meeting, Geneva, February 2008

A working lunch to discuss the AMC was held on February 19 during the Global Immunization Meeting in Geneva. The presentation was chaired by Joachim Hombach, Acting coordinator for implementation research at the World Health Organization's Initiative for Vaccine Research (IVR). Major issues discussed during the session included TPPs and regional specificity of AMC vaccines, the AMC structure, participation of emerging manufacturers, setting of tail price and choice of vaccines at country level. Representatives from industry, international organizations (including WHO and UNICEF), developing countries, and civil society organizations attended the session.

Pneumococcal Awareness Council of Experts (PACE), Istanbul, February, 2008

PACE is a working group of the world's leading experts in infectious diseases and vaccines. The Council's mission is to raise awareness of pneumococcal disease and advocate for its prevention through vaccination. Council members met for a working lunch during their participation in the 3rd Regional Pneumo Symposium in Istanbul. Members primarily discussed AMC mechanism and timeline with a view to incorporating AMC briefings in their pneumo awareness activities. Additional issues discussed at the meeting included AMC funds as well as AMC price and tail price setting.

BRIEFING ON THE AMC FOR GAVI ELIGIBLE COUNTRIES, 3 APRIL 2008, GENEVA

The AMC basic concept was presented as well as enhancement chosen for adoption by the AMC Donor Committee. In addition, presenters gave a brief talk on the history of the AMC idea, the work undertaken from launch to today as well as next steps and long term implications of the pilot project.

Main issues raised:

- AMC complementarity with other initiatives such as the Working Group on Intellectual Property for Health.
- Modalities for divulgation of more information to GAVI eligible countries.
- Availability of in-country support for participation in AMC pilot.
- AMC Partners preparedness against potential risks, including potential of industry breaking AMC rules.

GAVI eligible countries' missions positively received the briefing chaired by Nina Schwalbe – Deputy Executive Secretary, Director of Policy, GAVI Alliance. Presentations were given by:

- Chris Athayde, Head of Development Policy Unit, International Poverty Reduction Team, UK HM Treasury
- Mercy Ahun, Head of Country Support, GAVI Alliance
- Tania Cernuschi, AMC Secretariat, GAVI Alliance

Please see addendum six for a list of participants.

SECTION 3: MEETINGS WITH CIVIL SOCIETY ORGANIZATIONS, MAY – NOV 2007

May 2007: The Italian Ministry of Economy and Finances convened a meeting for GAVI on May 30 to introduce its work to Italian NGOs and update the group on the AMC and International Finance Facility for Immunization (IFFIm). The meeting was part of a series of regular meetings between the Ministry and the civil society on issues pertaining to international aid and development.

September 2007: Several meetings with various civil society organizations were convened throughout September 2007. A brief outline of these meetings is included below:

- GAVI met with senior Oxfam officials in September 2007. Oxfam expressed interest in GAVI's work in global health architecture.

- A Civil Society outreach event was convened in Oslo, Norway on September 17. The theme was *Access to vaccines for poor countries – Is there a role for AMC?* Around 40 participants (CSOs, academia, public officials) from Norway, Denmark and Sweden gathered in Oslo to discuss the role of the Pneumococcal AMC. In addition to an overview of AMCs from GAVI, the meeting included presentations and feedback on the AMC model from Norwegian Church Aid, AIDS Foundation (Denmark) and MSF/ACCESS Campaign.

- Representatives from GAVI presented the AMC concept at the Action for Global Health annual advocacy meeting in London. Meeting participants were briefed on the AMC in the context of innovative financing mechanisms.

November 12 – 13, 2007: A GAVI Alliance civil society meeting was held in Geneva 12-13 November. The meeting gathered more than 30 CSO participants. The objectives of the meeting were to:

- Increase awareness of CSOs as a key partner in the GAVI Alliance.
- Present and discuss perspectives of CSOs from the pilot countries and to receive recommendations for improvement of this pilot project. Each of the participants from the pilot countries were asked to make a short presentation regarding civil society contribution to immunization and child health in their respective country. The countries represented at the meeting included Ethiopia, Ghana, DR Congo, Bolivia, Georgia, Pakistan, and Indonesia.
- Ensure feedback on improvement of civil society representation and voice within GAVI Alliance governance structures at national, regional and global levels.
- Provide an update on AMC progress and solicit feedback on the design of the mechanism.

UK CSO consultations 2005 – 2006:

November 2005: The UK Department for International Development (DFID) consulted with industry, academics, NGOs, and other stakeholders to gain views on AMCs. The objective of these consultations was to widen understanding of and debate around AMCs, to share ideas and advance progress on consultation on AMCs more generally, and finally, to feed into design and development of AMCs for vaccines.

2006:
DFID representatives gave a presentation to the Stamp out Poverty network.

2007
DFID held informal meetings with Oxfam, MSF and SCF. GAVI also held formal consultations with each of these NGOs.

Canada CSO Consultations:

Oct 31, 2006: Finance Canada officials made a presentation to civil society and other stakeholders at the Canadian International Development Agency's (CIDA) International Development Days program.

Nov 5, 2007: CIDA organized an NGO outreach event on the pilot AMC as part of the Canadian Conference on International Health. Officials from various Canadian civil society organizations attended the event.

KEY OUTCOMES/RESULTS OF MEETINGS WITH CSOS
Several important topics were consistently raised by the CSOs:

- The rationale behind targeting pneumococcal vaccines and the importance of the other diseases under consideration
- The importance of sharing robust information on how the price is being set, how this delivers value for money and how the risks of over-paying have been mitigated.
- The importance of ensuring that co-pays and tail prices are sustainable and affordable for developing countries.

- The importance of rigorous analysis of whether an AMC is the best approach for improving health in poor countries.
- A number of NGOs expressed frustration with the global IP environment and asked whether the AMC could be used to alter IP laws".
- The importance of emerging suppliers being allowed to participate (many NGO's expressed scepticism that emerging suppliers would be allowed to produce vaccines within the AMC timeframe.)

BRIEFING ON THE AMC FOR CIVIL SOCIETY ORGANIZATIONS, 3 APRIL 2008 – GAVI OFFICES, GENEVA AND WASHINGTON

The briefing was held by videoconference in Geneva and DC and also included participants by phone. Participants in the briefing included representatives from the GAVI Alliance, Bill & Melinda Gates Foundation, World Bank, PATH, Center for Global Development, Aeras Global TB Vaccine Foundation, MSF, Oxfam, Knowledge Education International, Save the Children UK, the Swedish World Infection Fund, and BVGH. Briefers included:

- Chris Athayde, Head of Development Policy Unit, International Poverty Reduction Team, UK HM Treasury
- Ruth Levine, Vice President for Programs and Operations, Center for Global Development (via video)
- Nina Schwalbe, Deputy Executive Secretary, GAVI Alliance
- Tania Cernuschi, AMC Secretariat, GAVI Alliance

The AMC basic concept was presented as well as enhancement chosen for adoption by the AMC Donor Committee. In addition, the history of the AMC idea, and work performed from launch to today as well as next steps and long term implications.
Main issues raised:

- Plan for monitoring and evaluation of the pneumo AMC and opportunities for CSOs' input.
- Timing of the next AMC.
- Possibility to make public the analysis that informed the expert group's recommended modifications.
- Reasons for donors preference of frontloading of price versus firm order timing.
- MSF was very pleased that the issues they had raised previously were incorporated into the EEG report.

- Possibility to prepare consultation package to send to the biotech industry.

It was confirmed that the IWG would welcome additional inputs from civil society and developing countries. A follow up discussion between IWG members and MSF took place on May 8, 2008.

Please see addendum six for a list of participants.

SECTION 4: INDUSTRY CONSULTATIONS

JUNE - OCTOBER, 2007

GAVI, as the AMC Secretariat host, was requested to lead the consultations with vaccine suppliers, in close collaboration with the World Bank and the GAVI PneumoADIP. The consultations were used to gather feedback and comments on key elements of the Pneumococcal vaccine pilot AMC from vaccine suppliers; this information would in turn inform the detailed terms of the AMC agreements which are to be finalized in mid 2008.

During the consultations, potential suppliers were updated on the work done thus far, and their feedback was sought on AMC elements. Specifically, discussions with suppliers covered the following:

- The initial model used to estimate price per dose for the AMC, and the key assumptions that were used to generate these figures
- The options for the relationship between different payment and pricing elements of the AMC (the AMC price, country co-payments and the AMC tail price)
- Demand-related issues and ways to minimize demand uncertainty
- Supply obligations in the post-AMC period

The GAVI PneumoADIP identified vaccine companies with pneumococcal conjugate vaccine programs. Two multinational corporations (MNCs) and six emerging manufacturers (EMs) with active pneumococcal vaccine programs were visited, as were three vaccine MNCs that had worked on pneumococcal vaccines in the past.

Multinational Corporations	Emerging Manufacturers
Wyeth (U.S.) Merck (U.S.) SanofiPasteur (US/France) GlaxoSmithKline Biologicals (Belgium) Novartis (US/Switzerland)	Biological Evans (India) Shanta Biotechnics (India) Serum Institute of India (India) Panacea (India) Chengdu Institute of Biological Products (China) BioManguinhos/Fiocruz (Brazil)

The suppliers broadly welcomed the AMC, stressing that their feedback and suggestions should be seen as engagement in the AMC process. They also reiterated their commitment to the goal of finding new ways to supply vaccines to the world's poor in a sustainable manner. Industry also highlighted a number of concerns about AMC design and implementation.
These included:

- The importance of ensuring that the TPP did not add significant layers of regulation that would slow developing country access to vaccines
- That building additional, dedicated manufacturing capacity will require some form of demand risk mitigation
- That sufficient returns need to be considered in the AMC so that it does not represent a money-losing proposition
- That the total size of the AMC envelope was reasonable, although emerging suppliers expressed some concern about sufficient flexibility, particularly in the tail period given that they are required to make much longer commitments than is the industry standard.

Additional details from the supplier consultation process are included below:

Supplier comments on AMC mechanism: Suppliers indicated that the value proposition of the pneumococcal pilot AMC for them would depend on a series of factors including AMC size, price, post-AMC price, investment in R&D, and manufacturing capacity. Suppliers also raised concerns on measuring the success of the AMC pilot, and on convincing shareholders that there would be a sufficient return on investment in selling

pneumococcal vaccines to developing countries. Several MNCs expressed concern over making monetary investments in expanding existing facilities, or building new ones, based solely on the strength of the AMC.

Supplier comments on AMC key terms (size, price, post-AMC price): Suppliers raised concern over some of the data used to populate the AMC-FIRM model, indicating that they would prefer conducting their own modeling using propriety data. This would more accurately reflect their costs and support their internal decision-making on participating in the AMC. Regarding AMC pricing, EMs preferred prices toward the lower end of the proposed price range so as to extend the AMC period and allow them more time to enter the market during that time. On the other hand, MNCs expressed a preference towards the higher end of the price range in order to more quickly recoup their initial investment. Both EMs and MNCs recommended volume-related pricing as one way to effectively offset the demand risk. Finally, almost all suppliers stated that the post-AMC pricing is critical to their participation

Supplier comments on AMC design elements (supply terms, country co-pay, risk to suppliers/demand uncertainty): It was suggested that supplier obligations in the post-AMC period should be tied to the benefit received in the AMC period. Suppliers were supportive of a supply commitment based on either years of benefit or the volume of benefit. In addition, suppliers sought clarification on the country decision-making process, specifically how changes in country product preference would affect supplier obligations. Suppliers requested that this type of information be clarified in the Framework and Supply Agreements.

Citing demand risk concerns, suppliers were sceptical that countries would be able to afford even small co-pays during the AMC period, or the larger post-AMC prices that would follow. As a solution, suppliers suggested they be allowed to offer discounts to countries during the AMC period as a means of reducing (or even eliminating) the country co-pay. All suppliers cited demand uncertainty as the most problematic aspect of the AMC.

UK and Canada Supplier Consultations:
On January 8, 2008 HMT and DFID met with representatives from GSK and Wyeth. During the meeting, the companies reiterated the comments they had made earlier through the GAVI/Bank meeting consultations process. Also, on January 28, 2008, officials from Finance Canada and CIDA had a teleconference with officials from Wyeth, who were supportive of the AMC.

BRIEFING ON THE AMC FOR INDUSTRY, 4 APRIL 2008 – UNICEF SUPPLY DIVISION, COPENHAGEN

The AMC basic concept was presented as well as a review of the expert group process, concerns about the original framework design and the enhancements chosen for adoption by the AMC Donor Committee. In addition, Steve Hurst gave a brief talk on the history of the AMC idea, the work undertaken from launch to today as well as next steps and long term implications of the pilot project. Main issues raised:

- The lack of demand assurance or firm order timing by the donors as a problem for industry to shoulder risk of building new plants
- Concerns about how the tail price would be set and exactly what the cap meant and how it would be determined
- The importance from emerging suppliers at having them being able to benefit from the AMC; the sequential tender was felt to address this
- The importance of a next AMC to focus on earlier stage research-driven activities rather than this pilot which is primarily influencing capacity decisions

Please see addendum five for a list of participants.

INDUSTRY CONSULTATIONS ON DRAFT LEGAL AGREEMENTS DECEMBER 2008- JANUARY 2009

In December 2008, the AMC Stakeholders encouraged a final round of consultations on the Pneumococcal AMC through the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and Developing Country Vaccine Manufacturers Network (DCVMN).

GAVI, UNICEF and the World Bank shared the following suite of AMC draft legal agreements clarifying the terms and conditions of the pilot:

1. The AMC Offer Agreement including the AMC Terms & Conditions and the Pro-Forma Supply Agreement
2. Independent Assessment Committee Charter and Bylaws
3. The AMC Procedures Memorandum
4. The AMC Registered Manufacturer Agreement
5. The Master Definitions Schedule

Six manufacturers responded with comments/queries as part of the consultations. Industry was given approximately one month to provide written comments. These comments were then reviewed by GAVI, UNICEF, the World Bank and the AMC donors with the advice of the co-chairs of the Implementation Working Group. Advice was also provided by the Centre for Global Development (CGD).

All companies strongly supported the goal of the AMC to accelerate the availability of pneumococcal vaccines for children in poor countries. Emphasising the long term partnership between manufacturers and public health organizations entailed by the AMC, suppliers stressed their interest in collaborating towards the successful implementation of this pilot and similar future initiatives.

Many clarifications were asked, particularly around the mechanics of the AMC Terms and Conditions and industry provided useful feedback as to whether legal language was unclear or more detail was required

BACKGROUND MATERIALS

ADDENDUM 1
DISEASE EXPERT COMMITTEE

Disease Expert Committee Membership:

Chair, Disease Expert Committee: Minister Ntaba, Minister of Health, Malawi

Adrian Towse, Office of Health Economics, UK

David Fleming, Director of Global Health Strategies, Bill & Melinda Gates Foundation

Dr. Barakamfitiye, former WHO AFRO Director of Communicable Disease Division and head of Sub-regional office for West Africa

Joy Phumaphi, Asst. DG Family and Community Health, WHO

Maryann Chawo, Ministry of Health, Malawi

Merceline Dahl-Regis, Chair of the GAVI Independent Review Committee, Bahamas

Michael Conway, McKinsey & Co.

Paul Henri Lambert, Chair of the Global Advisory Committee on Vaccine Safety

Professor Adenike Grange, President of International Pediatrics Association, Nigeria

Professor Anthony Mbewu, President of the South African Medical Research Council

Steve Hurst, Senior Advisor to BioVentures for Global Health

Supamit Chunsuttiwat, Senior Medical Officer, Department of Public Health Thailand

Report of Disease Expert Committee:

All vaccines are highly desirable public health tools.

The Expert Committee (EC) evaluated the six vaccines proposed in Minister Tremonti's report, and recommends pneumococcal vaccines as the most suitable candidate for a demonstration AMC because of both its ability to rapidly demonstrate that the AMC concept works and because of its potential impact on the health of the target populations.

BACKGROUND MATERIALS

A number of factors were taken into consideration in making this recommendation including:

- This demonstration AMC provides the ability to rapidly measure the effectiveness of the AMC concept in influencing industry behaviour and to establish effective AMC implementation mechanisms;
- The science and technology for an effective pneumococcal vaccine are well understood;
- There is a robust pipeline that includes several efficacious vaccines for the target countries. However there is a need to accelerate their development and production for use in these countries.
- Pneumococcal vaccines are likely to fit into the existing delivery systems and so can be cost-effectively introduced;
- There is a high disease burden and concern about growing antibiotic resistance.

In recommending pneumococcal vaccines for the initial demonstration AMC, the EC wanted to underscore the importance of accelerating the development, scale-up and reduction in manufacturing costs of new vaccines that will have increased public health impact in the target developing countries. The EC encourages the IAC to take this intent into consideration when determining the Target Product Profile for pneumococcal vaccines.

The EC recommends a second demonstration AMC to test the impact of the AMC on early stage vaccines. While vaccines against HIV/AIDS, malaria and TB are all critically important, the EC concluded that given the state of the science for HIV/AIDS vaccines, increased levels of push funding would be more appropriate than an AMC at this time. The EC is of the view that both malaria and TB vaccines would be suitable candidates for a demonstration AMC. However, on balance the EC found a malaria vaccine with 80% or greater efficacy against severe disease to be a more suitable candidate for this demonstration AMC for the following reasons:

- Given the high number of candidates in the pipeline, there is greater potential for the AMC to focus industry's attention and accelerate the development of the most promising ones.
- The development process will be more rapid because the length of trials to establish efficacy would be shorter as malaria is an acute disease with a more defined target population.
- Malaria makes the vicious circle of poverty and ill health in the poorest countries even more acute.
- National demand for malaria vaccines in endemic countries is likely to be strong given the very high awareness of its human and economic impact.

BACKGROUND MATERIALS

In view of the dynamic nature of vaccine development and the need for recommendations from the EC to be based on up-to-date information, the EC is happy to reconvene if further recommendations for future AMCs are requested.

Enabling Recommendations

To maximize the impact of AMCs, the EC recommends the following complementary actions:

- Recognize the importance of the IAC and WHO pre-qualification processes being in harmony. The EC understands that ways to harmonize these two processes are already being explored. The EC recommends further exploration into how the knowledge and capacity of WHO might be leveraged to support the IAC process (e.g. defining product profile) and to ensure the timely pre-qualification of AMC-eligible vaccines.

- Assure the availability of financial and human resources to strengthen the capacity of countries to ensure the sustained delivery of vaccines.

- Explore mechanisms and dialogue with existing entities and donors to support governments to ensure adequate funding for the long-term, sustainable purchase of vaccines once the AMC is depleted.

- Support governments to make timely decisions regarding the introduction of the AMC vaccine.

- Improve the accuracy and timeliness of demand forecasts so as to reduce the demand risk faced by industry.

- Monitor and evaluate the progress of demonstration AMC(s).

Finally, as recommended in the report from Minister Tremonti, the EC strongly endorses the continued need for complementary push funding, and recommends coordination between push and pull for efficiency and maximum impact of funding… "Such a pull mechanism is not an alternative, but is highly complementary to other public and philanthropic interventions in the health sector and, more generally, in development aid."

BACKGROUND MATERIALS

ADDENDUM 2
AMC ADVISORY GROUP

AMC Advisory Group Membership:

Rudi Eggers, WHO

Shanelle Hall UNICEF

Ruth Levine, CDG

Owen Barder, CDG

Jessica Pickett, CDG

Wendy Taylor, BVGH

Dan Kress, Gates Foundation

Hannah Kettler, Gates Foundation

Michele Sumilas, Gates Foundation

Lew Barker, TB

Rob Hecht, IAVI

Patricia Roberts, MVI

Yvette Collymore, MVI

John Wecker, RotaADIP

Deborah Atherly, RotaADIP

Orin Levine, PneumoADIP

Bernard Shwartlander, Global Fund

BACKGROUND MATERIALS

Steve Brooke, HPV (PATH)

Marcos Espinal, Stop TB

Awa Marie Coll-Seck, Roll Back Malaria

Violaine Mitchell, Vaccine Financing Task Force

Rudi Daems, Industry

John Hurvitz, Legal expert

Developing countries:

Rehan Hafiz, MOH Pakistan

Neil Cameron, South Africa former Director of Communicable diseases, current Associate professor at Stellenboch University, Cape Town

Julie Milstien, (Consultant)

World Bank:

Amie Batson

Susan McAdams

Samantha Naidoo

Alastair West

Applied Strategies:

Sandy Wrobel

Craig Shaffer

Governments:

UK, James Droop

BACKGROUND MATERIALS

Italy, Leone Gianturco

AMC Advisory Group Terms of Reference (TORs):

Through discussion, document review and potentially other activities, provide input on:

- Criteria for prioritizing products for an AMC pilot
- Critical thinking on outstanding structural issues (e.g. post-AMC price, co-pays)
- Critical thinking on structure and composition of IAC
- Input on AMC implementation functions and criteria for site selection

These inputs will be used by GAVI and the World Bank to develop background papers for the G7.

BACKGROUND MATERIALS

AMC Pilot Proposals:

	HIV	HPV	Malaria	Pneumococcal	Rotavirus	Tuberculosis
Disease Burden and Rationale	▪ 3.1 m deaths in 2005 ▪ 40.3 m people currently infected ▪ women are half of adults LWHA and 60% in SSA ▪ Without vaccine or expansion of prevention efforts, ~ infected will more than double to 10.2 million a year by 2030.	▪ HPV infection causes cervical cancer, which is preventable ▪ 500,000 new cases cervical cancer; 60,00 cases of other anogenital and oropharyngel cancers; 50% of women infected with virus at some point ▪ Over 270,000 deaths among women/yr; ▪ Over 85% deaths are in developing countries	▪ Malaria is a major cause of anaemia, low birth rate and premature birth; twice as many indirect deaths as direct ▪ 350-500m episodes annually ▪ 1m deaths per year (including 0.8 to 1 M children) ▪ 80% of burden in SSA	▪ Causes pneumococcal meningitis and pneumonia; life-long disabilities caused by brain damage for many survivors ▪ 1.6m deaths per year (including 0.7-1.0m children) ▪ 70% of burden in SSA and South Asia	▪ Causes diarrhoea ▪ 2M hospitalizations per year ▪ 500,000 deaths; second leading cause of death among children under five ▪ More than 80% of rotavirus-related deaths occur in south Asia and sub-Saharan Africa	▪ Tuberculosis is the leading cause of death for HIV/AIDS patients ▪ 9M cases; 2 billion currently infected ▪ 2M deaths per year; second deadliest infectious disease (behind HIV/AIDS) ▪ 62 % of burden in SSA and South Asia

BACKGROUND MATERIALS

	HIV	HPV	Malaria	Pneumococcal	Rotavirus	Tuberculosis
Other Interventions	▪ New prevention interventions under development include microbicides, pre-exposure prophylaxis, and male circumcision ▪ Current prevention and treatment only partially effective and	▪ Screening and treatment: effective in developed countries ▪ Lack of access to services in developing countries make this ineffective at present ▪ Condom use-only partially effective for social reasons and because of transmission through skin.	▪ Resistance growing to current treatment interventions (including the most recent, artemisinin) ▪ Bednets (highly successful with 20% reduction in child mortality) are underdeployed (currently	▪ Interventions are primarily for treatment (antibiotics). ▪ These are becoming more ineffective and expensive due to antibiotic resistance.	▪ Oral rehydration therapy (ORT) is effective if children are able to consume; ▪ Limited use of ORT in low-income countries (as low as 18%)	▪ Treatments in general (both BCG and DOTS) are outdated and insufficient ▪ Drug resistance is widespread ▪ Diagnostics provide very low detection rate (40%) ▪ Current treatment for TB disease partially accessible and effective if full, supervised 6-9 months course followed with regular

BACKGROUND MATERIALS

	HIV	HPV	Malaria	Pneumococcal	Rotavirus	Tuberculosis
	accessible ▪ Women and girls particularly underserved with prevention tools		at 3 to 5 % coverage)			supervision;preventive treatment is not accessible.
Product Environment	▪ 30 candidate vaccines being tested in small-scale human trials; significant scientific challenges exist ▪ Proposed efficacy of 50% ▪ 1st large-scale efficacy trial completed in 2003,	▪ Two late stage development candidates (Merck/GSK); companies prioritising introduction in developed/large middle income countries ▪ 100 % efficacy in treating types 16 and 18 precancerous lesions which cause 70% of	▪ Little current industry incentive to work on a vaccine because of scientific complexity ▪ Total developing country market $1.1 B ▪ One Phase II / Phase III candidate (RTS,S by GSK) and 40	▪ Global immunisation market is $7bn (350m doses) of which $1.3bn for low income sector ▪ AMC likely to assure adequate supply of first generation products and accelerate second	▪ Global market size estimate: $1.5 – $2.3 billion; GAVI-eligible countries represent 15% of this ▪ Emerging suppliers in India, China and Brazil in development ▪ Two	▪ Six candidates currently in development; all early stage ▪ Three candidates in Phase 1 clinical trials ▪ 70% target efficacy ▪ Boost vaccine to existing BCG and replacement vaccines both under development

BACKGROUND MATERIALS

	HIV	HPV	Malaria	Pneumococcal	Rotavirus	Tuberculosis
	additional one underway ▪ Significant market uncertainties a central concern of the private sector /political pressure to sell at discounted price once a vaccine is developed	cases ▪ Should be effective in preventing 67% of cervical cancer cases	promising early-stage candidates ▪ RTS,S: - has been under accelerated development since 2000 under a strong public/private sector collaboration and received over $180 M in funds - 50% efficacy (Phase II / Phase III)	generation products ▪ One licensed product (Prevnar by Wyeth), one expected to be licensed by 2008 (Steptorix by GSK) and 20 future candidates (pre-clinical and one in Phase I). ▪ 9-valent vaccine demonstrated 83% efficacy in non-HIV children in SSA (South Africa)	products are currently licensed: - GSK Rotarix is 30 countries (85 % efficacy) - Merck Rotateq only approved in the US (98 % efficacy) - Likely to face production constraints beyond 5 years	

BACKGROUND MATERIALS

	HIV	HPV	Malaria	Pneumococcal	Rotavirus	Tuberculosis
Improved health benefits though AMC-accelerated vaccine availability	▪ IAVI study concludes vaccine would reduce annual no. of new infections by 1/3 to over 80% by 2030, depending on efficacy and coverage. ▪ Number of people spared from infection over 15 years would range from 30-70 m ▪ Total cost per DALY saved by AIDS Vaccine = $67 to $21	▪ If 98 percent effective at preventing persistent HPV infection –would reduce burden of cervical cancer by 51% over several decades. ▪ Prevention of up to 500,000 deaths each year by 2050	▪ Two AMCs proposed: - AMC 1 for the late stage low efficacy vaccine (50%) - AMC 2 for a next generation >80% efficacy vaccine ▪ AMC 1 (2011-2015): 60,000 deaths averted, cost per DALY saved is $115 ▪ AMC 2 (2016-2030): 2.2m deaths averted; Cost per DALY saved is $54	▪ Prevention of up to 3.3m childhood deaths by 2025 (280,000 by 2015), starting in 2010 ▪ Cost per DALY saved is ~$100 (conservative estimate) ▪ Without an AMC, no vaccines will reach the poorest countries before 2023	▪ Prevention of 1.4 million deaths ▪ At $5/dose, vaccine is $106 per DALY saved ▪ At $1 per dose, vaccine is $19 per DALY saved	▪ Two AMCs proposed - AMC 1: BCG replacement vaccine could avert 7.7M deaths; Cost per DALY saved is $5 to $16 - AMC 2: New TB vaccine to boost the effects of BCG could lead to further 40% reduction in deaths; Cost per DALY saved of $21 to $235

BACKGROUND MATERIALS

	HIV	HPV	Malaria	Pneumococcal	Rotavirus	Tuberculosis
Size of an AMC	▪ $3.3B (IAVI estimate) ▪ $5.5-6.0 (Applied Strategies)	▪ Range of between $1.9B (with price/dose at $4) to $1.4B (with price/dose at $8)	▪ AMC 1: $145m ▪ AMC 2: $2,500m	▪ $830m	▪ Range of between $615M to just over $1 billion	▪ $360 M for a replacement vaccine ▪ $3.8 billion for a new booster vaccine
Demand Estimates	▪ Moderate efficacy:260 m courses during initial period (demand) 49 m courses (uptake) ▪ High efficacy: 690 m courses (demand) 260m courses (uptake) ▪ IAVI general estimate: 200-300m courses over first 10 years ▪ New delivery	▪ Reaching 60M doses by 2023 and maintaining demand between 60M and 80M through 2030 ▪ Particular uncertainty of demand estimates: - Adolescent vaccine - Social barriers - Extensive web of IP-8-12 yrs remaining life ▪ New delivery	▪ AMC 1 (2011-2015): up to 16m doses per year ▪ AMC 2 (2016-2030): 100m doses per year by 2030	▪ 50m doses by 2015, maturing at 180m by 2025	▪ Reaching 150M doses by 2019 and maintaining demand between 150M and 175M through 2030	▪ AMC 1: Replacement vaccine: up to 55M doses/year by 2030 ▪ AMC 2: Boost vaccine: up to 105M doses/year by 2030

BACKGROUND MATERIALS

	HIV	HPV	Malaria	Pneumococcal	Rotavirus	Tuberculosis
	systems needed including to reach high-risk populations. Stigma important barrier.	systems needed. Stigma important barrier.				
Extent to which this disease will show that the AMC concept works	▪ key barrier: scientific ▪ key risk: scientific failure ▪ AMC would be cost-effective investment even if it brings a vaccine into widespread use a few years sooner (due to treatment costs etc.). ▪ Success measured by more R&D	▪ key barrier: commercial ▪ Two existing suppliers ensure little monopoly risk ▪ Result in increased capacity and lower pricing perhaps 5 years sooner than would otherwise be expected ▪ Opportunity to address significant gender inequity	▪ key barriers: commercial and scientific ▪ Pilots both early and late stage needs within one disease ▪ Removal of much scientific risk due to recent RTS,S breakthrough (showing proof of principal) ▪ Success measured as capacity building and	▪ key barrier: commercial ▪ Two existing suppliers ensure little monopoly risk ▪ Success measured as capacity building – easily measured and quick arrival (1-2yrs) expected	▪ key barrier: commercial ▪ Two existing suppliers ensure little monopoly risk ▪ Test of AMC mechanism to stimulate large-scale production to meet demand ▪ Impact would become apparent quickly	▪ key barrier: investment in early stage product development ▪ Test of AMC mechanisms to pull early-stage R&D ▪ Success defined by: speeding development of new vaccine; creation of sufficient supply; full adoption by countries.

BACKGROUND MATERIALS

	HIV	HPV	Malaria	Pneumococcal	Rotavirus	Tuberculosis
			increased activity level in early development			
Issues to note			▪ AMC deaths averted assumed significant increase in coverage of existing interventions (up to 50%) in line with meeting MDGs and therefore are likely underestimates			

BACKGROUND MATERIALS

ADDENDUM 3
TARGET PRODUCT PROFILE (TPP) EXPERT COMMITTEE ON PNEUMOCOCCAL VACCINE

TPP Expert Committee Membership:

Committee Chair: David Goldblatt - University College London Institute of Child Health and Great Ormond Street Hospital for Children NHS Trust, UK

Nihal Abeysinghe - Ministry of Healthcare and Nutrition, Expanded Program on Immunization, Sri Lanka

Pedro Alonso - University of Barcelona Instituto Nacional de Saude (Mozambique), Spain

Edwin Asturias - University del Valle Johns Hopkins University (USA), Guatemala

Fred Binka - University of Ghana, Department of Epidemiology and Disease Control, Ghana

Costante Ceccarini - Consultant, Italy

Carl Frasch - Frasch Biologics Consulting, USA

Rehan Abdu Hafiz - National Institute of Health, Expanded Program on Immunization, Pakistan

Karen Lewis-Bell - Ministry of Health, Family and Health Services, Expanded Program on Immunization, Jamaica

Pieter Neels - Federal Agency for Medicinal and Health Products, Belgium

Hanna Nohynek - National Public Health Institute, Department of vaccines, Finland

Colin Sanderson - London School of Hygiene and Tropical Medicine, Health Services Research Unit, UK

Peter Smith - London School of Hygiene and Tropical Medicine, Department of Epidemiology and Population Health, UK

Cynthia Whitney - Centers for Disease Control and Prevention, Respiratory Diseases Branch,

Division of Bacterial and Mycotic Diseases, USA

BACKGROUND MATERIALS

List of Stakeholders for TPP Consultation:

Marguerite Baxter, Novartis

Joel Calmet , Sanofi Pasteur, France

Mahima Datla, Biological Evans, India

Laura Efros, Merck, USA

John Furey, Wyeth, USA

Akira Homma, Bio-Manguinhos / Fiocruz, Brazil

Rajesh Jain, Panacea Biotech, India

S.V Kapre, Serum Institute, India

Yang Lingjiang, Chengdu Institute of Biological Products, China

Varaprasad Reddy, Shantha Biotech, India

Walter Vandersmissen, GSK, Belgium

Kathleen Vandendael, GSK, Belgium

Vicente Verez Bencomo, Finlay Institute, Cuba

Steven Black, Kaiser Permanente Vaccine Study Center

Ian Feavers, NIBSC, United Kingdom

Elwyn Griffiths, Biologics and Genetic Therapies Directorate, Health Canada

Ulrick Heiniger, University of Basel, Switzerland

Kathy Neuzil, University of Washington/PATH

Richard Pebody, Communicable Disease Surveillance Center, United Kingdom

Helen Rees, University of Witwatersrand, South Africa

Heinz-J. Schmitt, Johannes Gutenberg University, Germany (STIKO - standing committee on vaccination)

Anthony Scott, NetSPEAR, Wellcome Trust/KEMRI, Kenya

ADIP management committee members:

Harry Greenberg, Stanford University School of Medicine, USA

Brian Greenwood, London School of Hygiene and Tropical Medicine, United Kingdom.

Jan Hommgren, University of Göteborg (chair), Sweden

BACKGROUND MATERIALS

Regina Rabinovich, Bill and Melinda Gates Foundation, USA

Kevin Reilly, Formerly Wyeth Vaccines, USA

Permanent Observers of ADIP management committee:

Thomas Cherian, WHO Headquarters, IVB/EPI

John Clemens, International Vaccine Institute, Korea

Mathuram Santosham, Johns Hopkins Bloomberg School of Public Health, USA

Other participants:

Richard Adegbola, Medical Research Council Laboratories

Robin Biellik, PATH-Europe, France

Dana Dunne, GAVI Alliance, Switzerland

Luis Jodar, International Vaccine Institute, Korea

Hope Johnson, Johns Hopkins Bloomberg School of Public Health

Andrew Jones, GAVI Alliance, Switzerland

Maija Helena Käyhty, KTL National Public Health Institute, Finland

Keith Klugman, Emory University, USA

Maria Deborah Knoll, Johns Hopkins Bloomberg School of Public Health

Orin S Levine, Johns Hopkins Bloomberg School of Public Health

Dr Rosamund Lewis, GAVI Alliance, Switzerland

Katherine O'Brien, Johns Hopkins Bloomberg School of Public Health

Ann Ottosen, UNICEF Supply Division, Denmark

Arthur Lawrence Reingold, University of California, USA

George, Siberg, Consultant, USA

Georges Thiry, PATH-Europe, France

WHO Staff:

Teresa Maria Aguado, IVR/RPD

Adwoa Bentsi-Enchill, IVB/QSS

Aleksandra Caric, IVR/QSS

Thomas Cherian, IVB/EPI

Joachim Hombach, IVR/IMR

Raymond Hutubessy, IVR/IMR

BACKGROUND MATERIALS

Miloud Kaddar, IVB/EPI

Marie-Paule Kieny, IVB/IVR

Souleymane Kone, IVR/EPI

Radmila Mirzayeva, IVR/IMR

Wolfson, Dr Lara, IVR/IMR

David Wood, IVR/QSS

Tiequn Zhou, IVB/QSS

Patrick Zuber, IVB/EPI

BACKGROUND MATERIALS

ADDENDUM 4
ECONOMIC EXPERT GROUP

Economic Expert Group Membership:

Committee Chair: David Fleming, Director and Health Officer Public Health Department - Seattle & King County

Jonathan Levin, Associate Professor of Economics, Stanford University

Chris Snyder, Professor, Department of Economics, Dartmouth College

Steve Hurst, Chief Business Officer, Immune Tolerance Institute, Inc

Patricia Danzon, Celia Z. Moh Professor; Professor of Health Care Systems and Insurance and Risk Management; and

Chairperson of the Health Care Systems Department, University of Pennsylvania - Wharton School of Business

Ernie Berndt, Professor of Economics, Massachusetts Institute of Technology and National Bureau of Economic Research

Michael Kremer, Gates Professor of Developing Societies, Harvard University Department of Economics

Ruth Levine, Vice President for Programs and Operations, Center for Global Development

Tony Mbewu, President, South African medical research council, South African Medical Research Council

Tony Osei, Deputy Finance Minister, Ghana Ministry of Finance

Jose Suleman, Advisor to the Executive Director, Africa Constituency 1 - International Monetary Fund

Cosmos Musumali, Executive Director Health Services and Systems Programs, HSSP, Zambia

BACKGROUND MATERIALS

Economic Expert Group TOR:

Taking into account analysis and recommendations provided to date, the Expert Group will be responsible for proposing the AMC pricing and design for the approval of the Donor Committee, which is responsible for overseeing the establishment of the AMC and is composed of the AMC donors with a rotational chair.

This Expert Group will be an independent group and will produce a report assessing options and proposed ways forward. The Expert Group will draw on information from industry consultations and other sources so that it can produce recommendations that draw from as broad as possible a spectrum. In particular, the Expert Group members will be consulted to guide the information gathering function of the industry consultations to maximise the usefulness of the information.

These Terms of Reference will serve as a guide. Given the innovative nature of the AMC, issues may arise beyond the items covered here, and will be addressed as appropriate by the Donor Committee in consultation with the Chair of the Expert Group. The Expert Group will cease to exist upon completion of its report, unless otherwise decided by the Donor Committee.

BACKGROUND MATERIALS

ADDENDUM 5
IMPLEMENTATION WORKING GROUP MEMBERSHIP

MEMBER	TITLE	ORGANIZATION
David Fleming, co-chair	Director and Health Officer Public Health Department	Seattle & King County
Ruth Levine, co-chair	Vice President for Programs and Operations	Center for Global Development
Ann Ottosen	Contracts Officer, Immunization Team	UNICEF Supply Division
Thomas Soresen	Chief of Immunization	UNICEF Supply Division
Andrew Jones	Senior Programme Officer	GAVI Alliance
Tania Cernuschi	AMC Secretariat	GAVI Alliance
Jan Vandergoltz		World Bank
Susan McAdams		World Bank
Jonathan Levin	Associate Professor of Economics	Stanford University
Steve Hurst	Chief Business Officer	Immune Tolerance Institute Inc
Tasneem Chipty		CRA

IWG TERMS OF REFERENCE

Background

On March 10, 2008, the AMC Donor Committee discussed the Economic Expert Group's Report and agreed with its conclusion that modifications to the AMC structure could enhance the prospects of achieving AMC's objectives. Donors agreed to commission further work to recommend specific terms and parameters for an enhanced structure that would include industry supply commitments, frontloaded pricing, sequential tendering, and a tail price cap. Donors also expressed their wish to have further information on the potential for spot market purchasing before dedicated capacity becomes available.

Objective

Donors have decided to create an Implementation Working Group (IWG) with the task of recommending a specific proposal for the AMC structure and parameters, inclusive of the implementation features noted above. Donors expect the proposals to be detailed and operational so as to allow donors to finalize the detailed terms and features of the binding offer to be presented to industry in the legal documentation.

BACKGROUND MATERIALS

Responsibilities/Functions
The Group will recommend specific AMC terms that incorporate the features described below.

- Industry supply commitments

Specific recommendations for the relationship between a supply commitment and AMC funds. In particular, terms would include: i) minimum bid requirement for each firm/commitment, possibly complemented with a scale-up clause; ii) the starting date of the commitments; iii) their length, specifying whether it will be common to all bids (and if not the parameters determining it); iv) optimal amount of total supply commitments in doses. Recommendations for procedures in the event that supply commitments do not satisfy sufficient demand. Recommendations of specific provisions to avoid a situation in which AMC funds continue to be legally tied to a supply commitment for which here is no corresponding demand.

- Sequential tendering

Donors decided that sequential tendering could only be implemented for two bids, each with the same terms (this preferred option could be supplemented, if deemed advisable by the IWG, by an option for a strict rule-based second tender, with full details provided on the rule). Specific recommended terms should include: i) timing and size of the two bid rounds (including the possibility of specific triggers for the rounds); ii) possible limits on the timing of the bids in any of the two rounds; iii) provisions for the use of any unassigned funds in the first round of bids.
Given the above-mentioned limits posed by donors on the design of sequential tendering, donors wish to have an assessment of the effectiveness of sequential tendering (with optimally-chosen parameters, using saved DALYs as the relevant metric) with respect to an AMC design without this feature (the comparison made with the same metric).

- Frontloaded pricing

Recommendation on the specific parameters of frontloaded pricing as a measure to mitigate demand risk.

- Tail price cap

Recommendation of an exhaustive set of parameters to define an inflation-adjusted optimal tail price cap, with optimality being defined as a level that is set in a completely transparent way, and that balances the AMC goals of long-term affordability to low-income countries and scale-up of adequate production capacity. The donors have termed the anticipated tail price as "low and hard." Donors are willing to consider different options if sequential tendering is not feasible and the IWG deems them appropriate. Recommendations for increases in tail prices under conditions where underlying costs increase in unforeseen ways.

- Spot market

BACKGROUND MATERIALS

Explore the desirability and, if desirable, specify the features, and terms of an AMC spot market for purchasing doses from any pre-existing excess manufacturing capacity, including the specific details of the link between such purchases and the supply commitments under the AMC enhanced design.

- Expected outflows

For donors to fully assess the financial implications of the enhanced design, the expected time profile for the AMC outflows should be compared with the expected time profile of the donor contributions.

As time permits and in addition to the required parameters listed above, the IWG may provide guidance to the donors on additional issues that will need to be set prior to the completion of the offer, including: procedures for soliciting supply commitments and selecting among them; criteria for firm eligibility to bid on supply commitments; procedures for excluding countries from benefiting from a cap on the tail price as their national income increases; rules regarding treatment of India; penalties for breach and force majeure conditions; and rules regarding assistance with vaccine introduction for early adopters by donors and/or firms.

In order to fulfil these responsibilities, the IWG will:

1. Carry out any additional analytic work that may be needed to refine the AMC structure and recommend its final parameters.
2. Carry out focused consultations with industry to obtain information relevant to the above-mentioned design features. Such consultations will only take place after the public announcement of donors' decisions regarding the AMC design and be open to all firms. Any further specific aspect of industry consultations is to be decided by the Donor Committee.

Work will be undertaken primarily via e-mail and conference calls. It is not anticipated that an in-person meeting will be required.

Composition of the IWG

The IWG will consist of at most four experts from the Economic Expert Group as well as representatives of the World Bank, GAVI and UNICEF, at most two for each institution. The IWG will solicit advice and inputs from other members of the EEG as it deems necessary. Donors will participate in the IWG's meetings as observers (on a voluntary basis and in ways to be arranged by the IWG chair), but will not participate in the consultations with industry.

The group will be co-chaired by David Fleming and Ruth Levine, and secretarial functions will be carried out by GAVI. The analytical work deemed necessary by the IWG will be carried out and/or managed by the Center for Global Development (CGD) (economic analyses) and World Bank (legal analyses). Remuneration of consultants and economic experts serving in the IWG will be managed by CGD, under financial arrangements to be offered by the Donor Committee. On invitation of the co-chairs, the

BACKGROUND MATERIALS

Chair of the Donor Committee and/or other members of the Donor Committee may observe the work of the IWG.

Report and timeline

The findings of the IWG are to be presented in a Report, which should include operational recommendations and form the basis for donors' final decisions on AMC design and implementation and whose final version will be made public. It is understood that all the recommendations put forward in the Report will be operational and as specific as possible so as to allow swift incorporation into the legal documents. The Report will be completed and sent to donors by 11 May, 2008 (timeline may shift depending on donor needs; work must be completed by end of May).

The Chair and members of the IWG will update donors on the progress of the work via conference calls as deemed appropriate by either the IWG or the donors. Substantive questions or points of clarification on which the IWG would like to consult with the Donor Committee as a whole should be channelled through the Chair of the Donor Committee.

BACKGROUND MATERIALS

ADDENDUM 6
APRIL 2008 - ATTENDEES FOR CSO, DEVELOPING COUNTRY AND INDUSTRY UPDATE BRIEFINGS

List of participants from GAVI-eligible countries' missions to the United Nations Office at Geneva

Mission	Delegate attending
1. Afghanistan	Mr. Jai Akhshid, 2nd Secretary
2. Benin	Mr. Yao Amoussou, First Counsellor
3. Burkina Faso	Mrs. Aline Kansole Nébié, Representative
4. Cambodia	Ms. Eat Sonisa, Third Secretary
5. Congo	Mme Fernande Marie Christiane M'Vila, Counsellor to the Ambassador
6. Djibouti	His Excellency, Ambassador M.Mohamed Siad Doualeh
7. Haiti	Mr. Jean-Claude Pierre, Adviser to the Minister; Mr. Jean Bony Alexandre, Adviser to the Minister
8. Honduras	Ms. Yina Isabel Elvir, First Secretary
9. Indonesia	Ms. Indah Nuria Savitri, Third Secretary
10. Kenya	H.E. Ambassador Dr. Tom Mboya Okeyo
11. Kyrgyzstan	Ms. Saltanat Tashmatova, First Secretary
12. Lao People's Democratic Republic	Mr. Sanexay Sadettan, Second Secretary
13. Mauritania	Her Excellency, Ambassador Mounina MINT ABDELLAH
14. Moldova	Ms. Corina Calugaru, First Secretary
15. Mozambique	Mr. Juvenal Dengo, First Secretray, Charge for Labor and Social Affaires
16. Nepal	Mr. Bharat Raj Paudyal, Adviser to the Minister
17. Niger	H.E. Ambassador M. Adani Illo
18. Nigeria	Mr. Ezenwa C. Nwaobiola, 2nd secretary
19. Rwanda	Mr. Alphonse Kayitayire, First Counsellor
20. Sudan	Mr. Zahir Agab Ashi, Counsellor
21. Uganda	Mr. Justinian Kateera, First secretary
22. Ukraine	Ms. Svitlana Homanovska, Counsellor
23. United Republic of Tanzania	Mr. Deusdedit Kaganda, First Secretary
24. Yemen	Ambassador Dr. Ibrahim AL-ADOOFI; Dr. Essam AL-MAHBASHI, Third Secretary
25. Zambia	Ms. Peggy K. Mlewa, Firs Secretary

BACKGROUND MATERIALS

List of participants from Civil Society Organizations

CSO/Organisation	Delegate attending
1. Aga Khan Foundation	Ms. Sofia Jadavji
2. Baird's CMC	James Snodgrass, Senior Consultant
3. BIO Ventures for Global Health	Wendy Taylor, Founder & Vice President of Strategy and Operations
4. Caritas International	Francesca Merico, International Delegate
5. Center for Global Development	Ruth Levine (PRESENTER)
6. International Trade & Health Affairs	Jacqueline A. Keith, Vice President
7. Knowledge Ecology International	Judit Rius Sanjuan, Attorney
8. Knowledge Ecology International	Judit Rius Sanjuan, Attorney
9. MSF	Laurent Gadot, Access Campaign, Health economist
10. MSF	Tido von Schoen-Angerer, Executive Director
11. MSF	Daniel Pelletier
12. Oxfam America	Rohit Malpani, Senior Policy Advisor
13. PATH	Rachel Wilson, Policy and Advocacy
14. PATH	Eileen Quinn, Director, Communications & Advocacy, Vaccine Development
15. Save the Children UK	Dr. Selina Namchee Lo, Health Adviser
16. The PATH Malaria Vaccine Initiative	Alan Brooks, Director, Policy and Access
17. The PATH Malaria Vaccine Initiative	Vicky Cárdenas, MHS, PhD, JD, Program Officer, Policy and Access
18. World Infection Fund	Mr. Peter Lundström

BACKGROUND MATERIALS

List of participants from Industry

Manufacturer	Name of Participant	Position
(Heber) C.I.G.B.	Jorge Luis Vega Elías	
Berna	Yves Leurquin	EVP International and Government Affairs
Berna	Byung Lim Lee	Regional manager / International sales
BioFarma	Sarimuddin Sulaeman	Marketing Director
Biofarma	Juliman	Senior Manager for International Marketing
Biological E	Narender Mantena	Senior Vice-President SBD
Bio-Manguinhos/Fiocruz	Daniele Nunes	Commercial Division Manager
Bio-Manguinhos/Fiocruz	Cristiane Pereira	Market Relation Department Manager
Biovac	Dr. Morena Makhoana	
Birmex	SAMUEL PONCE DE LEON	General Director
Birmex	Francisco padilla catalan	Commercial deputy general director
Birmex	JESUS VARGUEZ AGUILAR	PLANNING DIRECTOR
Chumakov Institute	Alexander Kiktenko	Deputy Director Quality Control
Chumakov Institute	Andew Malkin	Chief of QA Division
GSK	Eunice Miranda	Director, Head of Global Commercial Affairs
GSK	Thomas Wijnands	Senior Tender Manager
GSK	Sheldon Poujade	Supranationals Key Account Manager
Indian Immunologicals	N S N Bhargav	Head-Exports
Institut Pasteur de Dakar	Philippe MAUCLERE	Director
InterVax Ltd.	Ray Tabbara	Director, Sales & Business Development
InterVax Ltd.	Marya Wright	Director of Marketing
Japan BGC	Naoki NAKADA	Manager
Japan BGC	Erina NAKA	
LGLS	Jeff Lee	Senior Manager
Merck	Stephen Faust	Global Vaccine Commercial Development
Merck	Elaine Esber	Executive Director
Novartis	Matthias Leuenberger	Head CommOps ME, Africa UNICEF & Japan
Novartis	Thomas Riedel	Regional Director Middle East, Pakistan, UNICEF
NVI	Roeland van Dam	Manager Marketing & Business Development
Panacea	Navita Khanna	Asstt.General Manager-Business Development & Licensing
Sanofi Pasteur	Pascal Perrin	VP International public markets
Sanofi Pasteur	Patrick LATURNUS	International tender director
Serum Inst. India	Mr. S. Mundra	Director
Serum Inst. India	Mr. Adar C. Poonawalla	Exec. Director - Operations
Shantha	Khalil Ahmed Shaikh	Executive Director
Shantha	Arun Kumar Biswas	Senior Vice-President (Exports)
SSI	Nies Thulstrup	Direcor Sales and Business Development
Torlak	Dr Mirjana Vignjevic Krastavcevic	Deputy Director Bacteriological Production
Torlak	Dr Vesna Kovacevic Jovanovic	Deputy Director Quality Control
Wyeth	Lynn Bodarky	Sr. Director