Pilot Advance Market Commitment
For Vaccines against Pneumococcal Diseases

December 15, 2008

Concessional Finance and Global Partnerships Vice Presidency
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<th>Abbreviation</th>
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<td>ACT</td>
<td>Accounting Department</td>
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<td>AIDS</td>
<td>Acquired Immune-Deficiency Syndrome</td>
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<td>AMC</td>
<td>Advance Market Commitment</td>
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<td>APPG</td>
<td>All-Party Parliamentary Group</td>
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<td>COGS</td>
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<td>DALY</td>
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<td>GAVI</td>
<td>Global Alliance for Vaccines and Immunization</td>
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<td>GDP</td>
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<td>IAC</td>
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<td>International Finance Facility for Immunisation</td>
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<td>NPV</td>
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Pilot Advance Market Commitment  
For Vaccines against Pneumococcal Diseases

Executive Summary

1. **Development Purpose.** This initiative tackles a longstanding development problem – persistent private sector failures to develop and produce products needed in developing countries, due to perceptions of insufficient demand or market uncertainty. The pilot focuses on the vaccine market, where research, development and production of vaccines specific to the needs of the poorest developing countries are limited by the small number of manufacturers, high cost of product development and capacity scale-up, and demand uncertainty.

2. **The Advance Market Commitment (AMC) Pilot Design.** The pilot AMC’s principal goal is to accelerate the creation of a viable market for pneumococcal vaccines for developing countries, by providing up-front financing to cover capital costs associated with the development of additional vaccine production capacity to meet demand from developing countries. The pilot’s focus is pneumococcal vaccines, for which the key technological issues have been resolved and there is substantial demand in poor developing countries. Pneumonial infections are the largest killer of children in Africa and worldwide, and pneumococcal infections are the largest cause of pneumonia deaths. The AMC pilot is expected to yield high benefits, saving an estimated 7.7 million lives by 2030 with a much lower estimated cost per DALY (Disability-Adjusted Life Year) saved (around $33) than the $100 benchmark cost for efficient health interventions in developing countries. Beyond its expected health outcomes, the pilot may validate the viability of the AMC concept for other uses.

3. **The specific design of the AMC pilot is intended to:**
   - spur development of vaccines needed in developing countries,
   - foster and accelerate dedicated production capacity scale-up,
   - provide a predictable and sustainable long-term price, and
   - address the high demand risk and demand uncertainty faced by the vaccine industry.

4. **Core AMC pilot funding from six donors will be $1.5 billion.** The six committed donors are Italy ($635 million); United Kingdom ($485 million); Canada ($200 million); Russia ($80 million); Norway ($50 million); and the Bill & Melinda Gates Foundation ($50 million). **Total spending for pneumococcal vaccines under the AMC pilot is estimated at roughly $9 billion between now and 2030,** including the $1.5 billion AMC subsidy from donors and $7.5 billion from the GAVI Alliance and GAVI-eligible countries during the AMC subsidy period and the post-subsidy tail period.

5. **Partner Support.** The GAVI Alliance (GAVI) will support the AMC operationally, assist countries with immunization program applications, and provide funding for vaccine purchases beyond the subsidy. Developing countries will apply for AMC-subsidized vaccines through GAVI’s country application process; **WHO will provide technical input to ensure vaccine quality; manufacturers of vaccines that meet the AMC requirements will enter into Supply Agreements with UNICEF, which procures vaccines funded by GAVI, all in accordance with the AMC terms and conditions.**

6. **The Bank’s Role.** The Bank has been closely engaged in the development of the pilot AMC for over three years, providing support to donors and leadership on health, finance and legal aspects of its design and implementation. **The Bank has been asked by donors to provide the financial platform for the pilot, and to place the $1.5 billion AMC subsidy from donors directly on IBRD’s balance sheet.**
7. **AMC on IBRD’s Balance Sheet.** As proposed, IBRD would receive AMC donor grants directly as “restricted assets”, with a corresponding liability, and would pass on the funds to GAVI subject to the AMC terms and conditions. Thus, the AMC pilot is expected to operate on a pure pass-through basis, with IBRD simply passing on funds it receives as they are needed. To provide enhanced assurance, IBRD would make an additional commitment to pass on AMC funds even if they are not received on schedule from donors. Specifically, IBRD would make an independent commitment to transfer donor funds to purchase AMC vaccines, (i) subject to specific requests from GAVI, (ii) in accordance with the AMC terms and conditions, (iii) and also subject to the schedule of donor payments, whether or not donors actually pay on schedule. IBRD would also provide standard financial management and administrative services with respect to donor contributions, AMC commitments, and disbursements.

8. **IBRD would charge the AMC program for its AMC-related administrative and financial management costs on a full cost-recovery basis.** In addition, IBRD would charge for its balance sheet commitment based on IBRD loan terms. As such, a 30 basis point charge would apply annually to IBRD’s outstanding exposure on grant payments owed from AMC donors. This charge is below that of market levels and reflects IBRD’s nature as a shareholder cooperative, consistent with the development purpose of the AMC pilot and use of AMC funds. Over the life of the AMC, the total charge is estimated at $25.6 million ($22 million in current dollar terms). The balance sheet commitment charge and administrative and financial costs are expected to be covered by investment income on AMC program balances.

9. **Key financial risks associated with putting the $1.5 billion AMC subsidy from donors on IBRD’s balance sheet include donor payment default or delay,** which will be mitigated by protections embodied in the AMC legal agreements, including specific enforcement remedies and indemnities in favor of IBRD in the legally binding grant agreements from donors. Donor commitments to the AMC pilot have been made at the highest political levels.

10. **Key operational risks include the possibility of failure of the AMC to attract industry participation,** notably if the pricing terms are inadequate or due to demand uncertainty. Operational risks may give rise to reputational risks for the Bank, since failure, whether or not due to causes within the Bank’s control, would result in associated reputational damage to the Bank. To minimize these risks, extensive work and consultations were undertaken to develop a sound design the AMC terms, in particular to set the AMC pricing structure within an appropriate range, and to develop a robust demand forecast. In addition, there are implementation risks associated with GAVI’s central role in the AMC. The Bank will use its multiple roles in GAVI to help ensure that GAVI’s responsibilities are successfully discharged.

11. **Management believes the AMC is worth undertaking despite the risks.** It is a carefully designed pilot, constructed with the benefit of lengthy consultation and input from a wide range of actors with extensive and varied expertise: developing countries and sponsoring governments, vaccine manufacturers and biotech firms, economists, academics, pediatricians, international financial, health and development institutions, CSOs, public-private partnerships, experts in law, public health, immunization policy and management, vaccine production. **The possibility of very high social and health benefits justifies taking the risk of project failure, or of public concern over economic profits to vaccine manufacturers that might arise in the case of success.** Management will report back to the Executive Directors on AMC progress annually.

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1 Full cost-based recovery of administrative and financial costs, charged annually to the AMC program, would take the place of the usual 25 basis point up-front fee on IBRD loans.
12. **Recommendations.** Management recommends that Executive Directors approve:

- IBRD agreeing to provide the financial platform supporting the pilot AMC for pneumococcal vaccines, consistent with its purposes under the Articles of Agreement;
- Placing the $1.5 billion AMC subsidy from donors on IBRD’s balance sheet, accepting donor grants as restricted assets subject to the AMC terms and conditions with a corresponding liability to pass through scheduled donor payments as needed for vaccine purchases;
- Charging the AMC program:
  - for administrative and financial management services on a full cost-recovery basis; and
  - a 30 basis point annual balance sheet commitment charge on outstanding exposure on AMC donor grants.

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**AMC Pilot Summary**

**Vaccine Eligibility (Target Product Profile):** Pneumococcal vaccine that is 60% effective in Africa and South Asia; includes the three most frequent strains found in GAVI-eligible countries; with a shelf life of at least 24 months.

**AMC Supply Agreement:** Agreement between vaccine manufacturer and UNICEF, entitling manufacturer to AMC subsidized price in exchange for commitment to supply a set number of doses of an eligible vaccine annually for ten years for purchase in GAVI-eligible countries.

**AMC Donor Funding:** $1.5 billion to cover the AMC subsidy paid to participating manufacturers to supply 200 million doses annually for ten years (at a rate of $3.50 per purchased dose, see below). Once the donor-funded subsidy has been paid in full, vaccines are purchased at the tail price.

**AMC Subsidy.** The $3.50 per dose subsidy entitlement is designed to cover capital costs associated with AMC-related plant capacity. The subsidy is paid during the “subsidy period”, i.e., the time when the participating manufacturer begins to supply vaccines until its subsidy entitlement is paid in full. The subsidy entitlement is calculated based on the share of the manufacturer supply commitment in the total target amount (200 million doses annually).

**AMC Tail Price:** Capped at $3.50 per dose, designed to cover variable manufacturing costs and paid during both the subsidy and “post-subsidy” period by GAVI. The tail price is subject to inflation review.

**Total AMC Subsidized Price:** $7 per dose (comprising the AMC subsidy plus the tail price) is paid to the participating manufacturer during the “subsidy period” only. If a manufacturer sets a tail price below $3.50, the per-dose subsidy amount will increase to maintain the AMC subsidized price at $7.

**Country Co-payment:** $0.10 to $0.30 per dose depending on income levels of GAVI-eligible countries.

**Total AMC spending:** Roughly $9 billion between now and 2030 including the $1.5 billion AMC subsidy and $7.5 billion in payments from GAVI (which is itself funded by donors) and recipient country co-payments during the AMC subsidy period and post-subsidy period.
PILOT ADVANCE MARKET COMMITMENT
FOR VACCINES AGAINST PNEUMOCOCCAL DISEASES

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Pilot Advance Market Commitment
For Vaccines against Pneumococcal Diseases

I. The AMC Concept

A. The Problem: Limited Supply of Affordable Vaccines in Poor Countries

1. More than 7 million people a year die from infectious diseases such as pneumococcal pneumonia, malaria, and tuberculosis, mostly in poor countries. Infectious diseases destroy human capital, limit growth, and constrain development; studies show a direct and quantifiable impact of improved health conditions on economic growth.

2. Immunization is one of the most effective ways to fight global infectious diseases, a primary cause of the mortality gap between high- and low-income countries. In the developing world, over two million children die each year from diseases that are already vaccine-preventable. New vaccines against rotavirus and pneumococcal disease, and a next generation of vaccines against malaria, tuberculosis and HIV/AIDS, could prevent millions more deaths and take a large step toward achieving critical health-related Millennium Development Goals.

Chart 1

3. Competition in the vaccine market is limited and slow-moving. The vaccine industry is highly concentrated, with five multinational suppliers dominating the market. Process know-how (rather than, for example, patent protection) is the critical barrier to the production of many vaccines. Other barriers to entry include extensive and rigorous regulatory oversight of this biological product, the long lead times for investment, and the high scientific and perceived market risks. As a result, vaccines come on the market from only a handful of suppliers, one supplier at a time. Generally, there is only one supplier in the market for the first three to five years of a new vaccine’s life.

4. Developing a new vaccine entails substantial scientific challenges as well as large investments, and can take up to twenty years. Given the expensive, lengthy and uncertain product development process for vaccines (Chart 2), industry’s focus has been to develop “blockbuster” products that focus on diseases, strains and desired characteristics for industrial country markets. Well

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2 In 2003, five multinational corporations (GlaxoSmithKline, Merck, Novartis, Sanofi Pasteur, and Wyeth) accounted for 70% of the worldwide market for vaccines; by 2005, they accounted for 82% of the market.
over 70% of the global vaccine market of roughly $8 billion comes from sales in industrial countries, home to about 15% of the world’s population. By contrast, well under 10% of sales are for use in low-income developing countries.3

5. **For a vaccine to have the maximum health impact in low-income developing countries, additional investment is needed to tailor the vaccine to special epidemiological and logistical needs.** Investment is needed, for example, to include additional serotypes that are prevalent in developing countries or to design appropriate packaging so the vaccine is suitable for existing delivery systems. Use in developing countries also requires significant incremental investments in production capacity to ensure adequate supply to meet global needs rather than just the needs of industrial countries. Building production capacity is a lengthy, four to five-year process, which means that the decision to build capacity is made before final data are available on a vaccine’s efficacy.

6. **Vaccines for use in low-income countries face additional uncertainties and risks.** Low-income countries are unlikely to be able to afford prices high enough to ensure that investment costs are recovered, and reliance on unpredictable donor funding does not alleviate demand uncertainty. Despite increases in funding for developing country health systems generally and for immunization programs specifically, there is still not enough committed, predictable money to support the introduction of many priority health products, including needed vaccines. As a result, manufacturers and many developing countries still perceive the future availability of public funds to purchase new vaccines as uncertain.

7. **Unpredictable demand in developing countries has been particularly harmful to vaccine access because of a number of unique characteristics in the vaccine industry and market.** Vaccines are primarily purchased by governments. Often, as a result, demand is not smooth, as large requests come from large countries. Demand is also subject to the unpredictability of donor-dependent public budgets. Even where funding is available, weak health systems and slow decision-making may constrain actual uptake.

8. **For these reasons, the developing country market for vaccines has been perceived by industry to be small (despite its potential size), particularly risky and unpredictable, and not profitable enough to warrant the volume of investment that would be desirable from a public health point of view.** There have been recent improvements. The establishment of the GAVI

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3 Similarly, health R&D for wealthy countries totals over $100 billion, in a fairly even split between public and private funds, while for poor countries it is about $8 billion, mostly from public funds. Global Forum for Health Research, *The 10/90 report on health research 2003–2004*. (Geneva: Global Forum for Health Research; 2004.)
Alliance (GAVI)\(^4\) has substantially increased vaccine coverage worldwide for underused vaccines.\(^5\) In addition, vaccine procurement has been pooled through entities like UNICEF which purchase vaccines on behalf of more than 60 low-income countries. Nevertheless, market uncertainties continue to constrain investment to supply and introduce new vaccines into developing countries. An assurance to industry of a future market for needed vaccines and to governments of predictable donor funding is needed to overcome the uncertainties that have dominated vaccine access in developing countries to date.

**B. The Response: An AMC Can Provide an Assured Market**

9. **In such a context, an AMC may provide an effective response.** The AMC concept may be understood in different ways. It is defined here as a funding commitment, made in advance, designed to spur the creation of a market that does not yet exist or functions poorly. Generically, an AMC works as follows: First, donors commit to fund an AMC of a specified market size and price for a product with specifications targeting effectiveness and development impact in developing countries. Second, as and when candidate products become available, a credible independent body determines if new products meet the target specifications. Approval by that independent body entitles a manufacturer to enter into a supply agreement giving it access to AMC funds which subsidize purchase of the target product. Finally, when AMC funding is depleted, the manufacturer continues to provide the product at an established tail price for a specified period to meet continuing demand.

10. Based on this concept, donors created a pilot AMC for pneumococcal vaccines as an up-front financial commitment on their part to subsidize purchase of vaccines that meet a specified target product profile (TPP). The pilot AMC could both save lives in the near term and potentially “prove” the AMC concept – or demonstrate flaws in the structure.

**II. Pilot AMC Design**

**A. Choice of Target Disease**

11. In December 2005, in response to a report from Italian Finance Minister Tremonti on AMCs for vaccines, the G7 Finance Ministers agreed to develop a specific AMC pilot proposal. They asked the Bank and GAVI to take the proposal forward. An expert committee\(^6\) was convened to assess which of six candidate diseases of global importance would be the most appropriate for an AMC pilot: HIV/AIDS, malaria, tuberculosis, pneumococcal, rotavirus, or human papilloma virus. **Pneumococcal vaccines were chosen as the most suitable candidate for the AMC pilot for a number of reasons,** elaborated below.

12. **Substantial need.** Pneumococcal disease has devastating impact in developing countries. It is the leading cause of child pneumonia deaths, as well as the second leading cause of childhood

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\(^4\) Formerly the Global Alliance for Vaccines and Immunization.

\(^5\) Coverage in Africa of the DTP vaccine (diphtheria, tetanus, pertussis) increased from 44% to 77% between 1999 and 2007 (GAVI was established in 2000). Hepatitis B coverage in all GAVI-eligible countries increased from negligible levels to about 50% in the same period. GAVI Alliance Secretariat, 2008.

\(^6\) The independent Expert Committee comprised experts (nearly two thirds from developing countries) in public health, epidemiology, industry economics, vaccine development and law. The committee evaluated the six vaccines identified in the AMC Report prepared by Minister Tremonti of Italy, concluded that all six vaccines would benefit from AMCs in due course and that pneumococcal vaccines were the most suitable candidate for a demonstration AMC, and recommended a second demonstration malaria AMC for early-stage vaccines.
meningitis deaths. Every year, it kills more than 1.6 million people including 700,000 to 1 million children under age five. HIV/AIDS is increasing the rate of infections, with HIV-infected children 20 to 40 times more likely to get pneumococcal diseases. Growing antibiotic resistance is also making pneumococcal disease more difficult and expensive to treat. Pneumococcal-related child deaths alone cost some 21 million Disability-Adjusted Life Years (DALYs) per year; the inclusion of adult deaths and non-fatal cases might double that estimated burden. Pneumococcal disease also causes economic losses from premature adult deaths, reduced productivity of child survivors, and treatment costs. Pneumococcal vaccines can significantly reduce these losses and increase overall population health through herd immunity.7 (Herd immunity, or community immunity, occurs when the vaccination of a portion of the population (or herd) provides protection to unprotected individuals as well.) A pneumococcal vaccine trial of an early candidate in the Gambia reduced all-cause mortality by 16% or 7.4 per 1000 children under 30 months.8

13. **Need for a suitable pneumococcal vaccine.** Although a pneumococcal vaccine currently exists, its formulation is not optimal against the major strains found in poor countries. There are a number of improved pneumococcal vaccines at various stages of development, but historically it has taken 15-20 years on average for new vaccines to be affordable and available to developing countries. The pilot AMC aims to reduce the delay, with the first AMC-eligible vaccine available by 2009, a second by 2010.

14. **Vaccines are the most reliable and efficient way to prevent pneumococcal infections,** due to weak treatment systems, antibiotic resistance, threats of influenza pandemics, and the availability of robust immunization systems in most countries. Early vaccines and current candidate vaccines fit within existing immunization delivery systems, and they improve child survival in the communities where the disease burden is greatest. Herd immunity protection of older children and adults will make the vaccine even more cost-effective by preventing illnesses and deaths without requiring additional vaccination costs.

15. **Demand.** Governments in GAVI-eligible developing countries – countries with a 2003 per capita GNI of $1,000 or less – indicate that with acceptable financing and pricing terms there is substantial demand for pneumococcal vaccines. This interest is based on high recognition of the disease burden of pneumonia and meningitis. It has been supported by over 30 government letters of intent to GAVI confirming their expected introduction of pneumococcal vaccines into national programs.

16. It may be noted that the international public health community has a poor track record in estimating vaccine uptake, mistaking public health needs with real market demand. **To address the unusually high demand risk and demand uncertainty faced by industry,** considerable time and attention was spent on ensuring that the AMC demand forecast is as accurate as possible. The forecast assesses future demand country by country, taking into account each country’s implementation record of introducing vaccines in the past as well as the population cohort expected to be immunized. The forecast was also informed by country consultations and by government letters of interest to GAVI. (See Chart 3.)

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17. **Supply.** The pneumococcal vaccine pipeline includes one licensed product and several candidate vaccines in varying stages of development, increasing the possibility that a competitive market may result from the AMC incentive. The one licensed vaccine against pneumococcal diseases has been used safely and effectively since 2000 to vaccinate more than 30 million children in industrial countries. Capacity is minimal, however, and the vaccine is not considered suitable for widespread introduction in developing countries. Two new vaccines that meet the AMC’s requirements for populations in both developing and industrial countries may be licensed by 2010. Other vaccines, including from emerging market manufacturers, may come to the market in the following five to ten years. Participation in the AMC by a lower-cost emerging market supplier would help assure long-term sustainable supply capacity to developing countries.

18. **Speed of impact and of proof of AMC concept.** The obstacles to industry decisions to accelerate introduction of pneumococcal vaccines are commercial, not scientific. Because eligible vaccines can be ready in the near term, a pilot AMC for pneumococcal vaccines will quickly demonstrate success or problems with the AMC structure.

**B. AMC Subsidy Funding**

19. The pilot AMC’s core funding, from six donors, will be $1.5 billion. **The size of the $1.5 billion AMC subsidy was designed to compensate for capital investment costs incurred by participating manufacturers, assuming a neutral or positive risk-adjusted NPV.** The $1.5 billion is based on what is known about likely cost of goods for the one licensed pneumococcal vaccine and the two candidate vaccines furthest along the development pipeline.

20. **The AMC financial structure needs to provide assurance that the $1.5 billion AMC subsidy, in nominal terms, will be available to be disbursed to purchase eligible vaccines as needed.** That assurance derives primarily from the AMC’s assets: donor grants that are legally
binding and enforceable. Each donor will execute an unconditional grant instrument in the full amount of its contribution and with associated, specific payment schedules or a conditional grant instrument with payments made in accordance with specific demand-based requests from GAVI. Payments may be made earlier than scheduled, but not later. Italy, which has led the AMC initiative since the June 2005 meeting of G7 finance ministers, will contribute $635 million. The United Kingdom provided the initial impetus to include AMCs on the G7/G8 agenda, and will contribute $485 million. Canada spurred the launch of the pilot by being the first to make a specific pledge, and has committed $200 million. Russia will contribute $80 million, and led the G8 process in 2006 when the initiative came up for decision. Norway, a strong supporter of international health initiatives and immunization, will contribute $50 million. The Bill & Melinda Gates Foundation sponsored the original AMC working group led by the Center for Global Development, and will contribute $50 million.

C. AMC Pilot Terms: A specific structure to address a specific market failure

21. The specific terms of the AMC pilot were agreed by IBRD, GAVI, donors and independent experts. Total spending for pneumococcal vaccines under the AMC pilot is estimated at roughly $9 billion between now and 2030, including the $1.5 billion AMC subsidy from donors and $7.5 billion from GAVI during the AMC subsidy period and the post-subsidy tail period. GAVI is primarily donor-funded (see paragraph 85 below). It is expected that, consistent with GAVI’s co-payment policies, GAVI will gradually pass on more of the cost to countries over the course of the AMC. AMC co-payments from developing countries are currently projected at $0.10 to $0.30 per dose depending on income levels.

22. The pilot AMC target product profile (TPP) is designed to ensure that AMC funds are used for vaccines with high public health impact in poor countries. Establishing the TPP in advance reduces uncertainty. From the perspective of donors, the TPP helps assure good value for money by requiring AMC vaccines to meet high standards. For developing countries, it allows confidence that the vaccines procured through the AMC will have a high health impact locally and fit well within existing health and immunization systems. For industry, it provides clarity about the minimum product characteristics for vaccine formulation years in advance of the vaccine’s purchase.

23. AMC funding is available to any manufacturer that produces a new vaccine that meets the TPP. The TPP, established by an expert group convened by WHO and endorsed by the AMC Independent Assessment Committee (IAC), requires that eligible pneumococcal conjugate vaccines must meet several key product characteristics. In addition to being proven safe and effective, the TPP requires that AMC eligible vaccines:

- include serotypes 1, 5, and 14, strains that are highly prevalent in Africa and South Asia and relatively less prevalent in high income countries (that is, the TPP requires suppliers to include serotypes that market forces might otherwise lead them to omit);
- include the strains of pneumococcal disease responsible for at least 60% of serious disease in any given region; and
- be packaged in vials that have a shelf life of at least 24 months and are designed to fit with developing country delivery system requirements.

24. To spur production capacity scale-up, the pilot AMC will offer $1.5 billion in subsidies in exchange for commitments by manufacturers to supply a target level of 200 million doses annually for ten years. The subsidy entitlement is based on the manufacturer’s share of committed supply (the number of doses it commits to supply annually divided by the annual target supply level of 200 million doses). For example, a manufacturer that agrees to provide 10 million doses of an eligible
vaccine annually for ten years would be entitled to a subsidy of $75 million. For a supplier providing vaccines at the agreed committed capacity under its supply agreement, the subsidy will be paid out in approximately two years. This frontloaded payout of the AMC subsidy will allow manufacturers to recover cover capital costs associated with AMC-related plant capacity more quickly.

25. **Installing new capacity can take up to five years, so supply commitments will be accepted over time, up to the projected demand five years ahead.** Manufacturer may enter into multiple supply agreements over time, depending on competition and the level of unfilled demand over the next succeeding five years. (See possible scenario, Chart 4.)

![Chart 4](image)

26. **The AMC subsidized price is set at $7 per dose (comprising a subsidy payout rate of at least $3.50 plus the tail price of up to $3.50).** The subsidy component is meant to cover capital costs associated with AMC-related plant capacity while the tail price is designed to cover variable costs. The subsidized price of $7 per dose is paid during the “subsidy period” only, that is, the period when the participating manufacturer begins to supply vaccines until its subsidy entitlement is paid in full. Subsequently, vaccine purchases under that supply agreement will be made at the tail price only.

27. **To ensure a long-term, predictable, sustainable price,** manufacturers will commit to providing their agreed annual number of doses at a capped per-dose price that will apply once the subsidy has been fully paid. This “tail price cap” is initially set at $3.50. (Chart 5 shows how an AMC supply agreement works.) The **long-term price signal to developing countries will be the $3.50 tail price** per dose paid by GAVI; this is in the price range of other vaccines recently introduced in developing countries such as pentavalent vaccine.9

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9 Pentavalent vaccines immunize, in a single shot, against five infectious diseases: diphtheria, tetanus, pertussis, *Haemophilus influenzae* type b (Hib), and hepatitis.
28. Over the ten-year supply commitment period, combining the $7 subsidy price and a $3.50 tail price results in an average price to manufacturers of up to $4.25 per dose. As a basis of comparison, Prevnar, the only existing pneumococcal vaccine (but one which does not contain the necessary strains to meet the AMC’s required target profile) sells for $66-$84 per dose in the United States.10

29. To mitigate demand risk to manufacturers, a demand guarantee of 45% of one year’s demand is spread out over the first three years of the supply obligation to ensure payment of a small share of the subsidy entitlement of each firm. (The AMC secretariat in GAVI, assisted by expert advice, will conduct regular reviews of estimated demand, country by country, throughout the life of the AMC.) An opt-out provision will also allow relief from a firm’s supply obligation if demand for its product fails to materialize.

30. A manufacturer that is building new capacity to meet its AMC capacity commitment may also have some existing but not fully utilized production capacity for the AMC-eligible vaccine. In order to encourage supply adequate to meet expected demand, the manufacturer may make subsidized AMC sales out of any such “headroom” capacity. Suppliers will receive the AMC price of $7 for these sales. Providing access to the vaccine in advance of new manufacturing capacity coming onstream will help mitigate the risk of severe product shortage in the early years. From the manufacturer’s perspective, headroom sales will accelerate receipt of the AMC subsidy, increasing its value.

31. The tail price cap is not inflation-indexed. However, at the request of industry, the tail price cap can be reassessed and adjusted at three-year intervals or when there is a cumulative 7% rise in inflation, whichever comes first. Firms that agree initially to set a tail price lower than the cap will be permitted to increase the tail price at the rate of the OECD GDP deflator until the tail price reaches the tail price cap.

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10 The Centers for Disease Control (CDC) in the United States list the CDC cost per dose of Prevnar as $66 and its private sector price as $84 of November 2008.
32. Chart 6 illustrates a scenario under which the full AMC forecasted demand is met by different suppliers. Illustrative cashflows for a possible baseline scenario are detailed in Annex 1.

**Chart 6**

**Demand Forecast by AMC Supplier**

(assuming AMC supply commitments meet demand through 2020)

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D. Role of Implementing Partners

33. The path of AMC subsidy funds from donor contributions to the purchase of vaccines from manufacturers for use in developing countries will rely on IBRD and the AMC implementing partners: GAVI, WHO and UNICEF, as well as the Independent Assessment Committee. WHO and UNICEF, both of whom are GAVI implementing partners, will ensure delivery of vaccine in-country and integration of the AMC into existing processes. (Chart 7 summarizes the AMC structure.)

**Chart 7**

**AMC Structure**
34. **GAVI** was established as a public-private partnership mandated to improve child health in the poorest countries by extending the reach and quality of immunization coverage within strengthened health services. GAVI support is designed to accelerate vaccine uptake and to improve vaccine supply security through predictable, sustainable funding. In the AMC partnership, GAVI (and GAVI recipient countries with respect to their co-payments) will be responsible for paying the “tail price” portion (up to $3.50 per dose) of AMC-eligible vaccines, during both the AMC subsidy and tail periods. It will manage recipient country applications for vaccines, and pay for shipping, delivery, and other related costs (an expected 19¢ per dose).

35. GAVI will also host the AMC Secretariat, supporting meetings of the Independent Assessment Committee and its work. It will support AMC donor meetings and report regularly on the progress of the pilot AMC. It will be responsible for reviewing and updating the demand forecasts. It will liaise with all AMC partners, working closely with IBRD, WHO and UNICEF on vaccine demand, prequalification, procurement and payment issues.

36. **WHO** provides a central quality control function for immunization globally and the AMC specifically. It establishes guidelines for determining which vaccines are most appropriate and how to run an immunization program, and approves vaccines in principle for procurement by UN agencies. In the AMC, WHO will: provide recommendations, approved by its Strategic Advisory Group of Experts (SAGE), on vaccine TPPs; conduct the prequalification process for AMC-eligible vaccines to be purchased through UNICEF; and convene expert groups and provide technical advice and recommendations as requested by the Independent Assessment Committee on issues such as the introduction of new vaccines and health-system financing to governments of AMC-eligible countries.

37. **UNICEF** acts as procurement agent for most low-income countries, ensuring vaccine quality, low prices and reliable supply. UNICEF’s Supply Division will act as procurement agent on behalf of GAVI for the AMC. UNICEF will: negotiate final Supply Agreements with each AMC eligible vaccine manufacturer; place orders for vaccines on behalf of GAVI/GAVI-eligible, low income countries; collect the AMC subsidy and tail price payments from GAVI and the relevant co-payment from recipient countries; and arrange shipment/delivery of the vaccine to each GAVI-eligible country.

38. **Independent Assessment Committee.** The IAC, created under the legal agreements, is a cornerstone of the AMC. IAC members are appointed and overseen by an IAC Selection and Oversight Panel comprising individual members from IBRD, GAVI, WHO, the International Federation of Pharmaceutical Manufacturers, and the Developing Country Vaccine Manufacturers Network. IAC members have (and are required to have) background and expertise in public health, health economics, vaccine business development, contract law and developing country clinical performance and vaccine delivery systems. The IAC will oversee core parts of the AMC process, including approving the establishment of TPPs for candidate vaccines and ascertaining whether they are met. AMC credibility rests largely on the perception of industry, donors and developing country governments that the IAC is independent, fair and reliable. The IAC has the authority to convene expert groups; oversee the adoption of TPPs; monitor and report scientific progress; determine whether or not a candidate vaccine meets the TPP; and modify AMC terms in certain circumstance (such as adjusting the tail price cap). The IAC will provide a dispute resolution function on AMC technical aspects. The AMC secretariat in GAVI will provide administrative support to the IAC.
E. AMC Structure

39. The way the AMC will work, and the roles and responsibilities of all parties, will be established and governed by the AMC legal agreements. It is not contemplated that any new legal entity will be established. Rather, the parties will assume responsibility, as a contractual matter, for the functions of the AMC (see Annex 3). The core agreements are as follows:

1. A Stakeholders Agreement between IBRD, all donors, and GAVI will detail the AMC process, structure, and stakeholder roles and responsibilities.
2. An Offer Agreement between GAVI and IBRD will define the unilateral AMC offer to manufacturers.
3. The Terms and Conditions of participation in and eligibility for the AMC subsidy will be attached to the Offer Agreement, and other agreements as appropriate.
4. Grant Agreements will lay out the terms and schedule of grant payments from each donor to IBRD.
5. A pro forma Supply Agreement will be attached to the Offer Agreement. It will establish, in advance, key terms of the bilateral supply agreement between a qualifying manufacturer and UNICEF.
6. The IAC Charter and By-Laws will set out the role and responsibilities of the Independent Assessment Committee, including approving candidate vaccines, deciding on requested changes to AMC pricing terms (e.g. for inflation or fundamental changes in regulatory requirements), and convening appropriately constituted expert groups for technical assistance as necessary.

40. Once the establishing agreements are signed, donors will begin to make AMC payments to IBRD according to their payment schedules. GAVI and IBRD will put in place the AMC support structures, and the development and scale-up of pneumococcal vaccines to meet AMC goals will be monitored through the AMC secretariat within GAVI. Each firm will evaluate the AMC and determine the extent of its own investment in pneumococcal vaccine development and capacity to serve the target AMC countries. When a manufacturer produces a target vaccine, the IAC evaluates whether or not the vaccine meets the TPP requirements in coordination with WHO’s pre-qualification process. With an approved vaccine, the manufacturer enters into a supply agreement consistent with the terms of the AMC terms and conditions. Once supply agreements are signed, procurement and delivery of vaccines to GAVI-eligible countries and payments to industry will be supported primarily by GAVI and UNICEF.

41. A Donors Committee has been overseeing AMC implementation, providing input into the technical design and processes for the AMC. Once the AMC is established, an AMC stakeholders committee of all donors, IBRD and GAVI will meet regularly, monitor the implementation and progress of the AMC toward its objectives, and serve as a forum for consultation as necessary.

42. The AMC is structured to achieve its goals by providing long-term funding assurance to manufacturers and to developing countries. Nonetheless, the legal arrangements do provide limited circumstances in which funding can be suspended or cancelled in the events that would impair the AMC’s effectiveness. These include non-compliance or incapacity on the part of a specific manufacturer or manufacturers, the suspension or withdrawal of a vaccine license or its WHO prequalification status, or some fundamental change that would make the AMC’s objectives obsolete.
AMC Process and Flow of Funds

- Donors make grant payments to IBRD, each donor paying in accordance with its specific schedule or agreed demand-based payment arrangement.

- IBRD holds donor payments on its balance sheet, as restricted assets with a corresponding liability to pass through the payments for the benefit of GAVI under the AMC terms and conditions. Notional investment income is allocated to the AMC program balances.

- Countries apply to GAVI for AMC funding for pneumococcal vaccines. Countries must meet GAVI criteria designed to ensure a multi-year immunization plan is in place, synchronized with an overall health sector plan and supported by the finance ministry and national coordination body. Proposals are assessed on a first-come, first-served basis by an Independent Review Committee and approved by the GAVI Board.

- Once a vaccine is approved by the AMC Independent Assessment Committee as meeting the required target product profile, its manufacturer enters into one or more Supply Agreements with UNICEF consistent with the AMC terms and conditions.

- UNICEF procures AMC-eligible vaccines. All AMC vaccine purchases are initially sold at $7 per dose, comprising the applicable tail price (set by each manufacturer subject to the tail price cap) plus the per-dose subsidy amount. When the full subsidy amount has been paid, purchases take place at the tail price.

- The total subsidy entitlement paid to each manufacturer is the AMC subsidy, $1.5 billion, times the manufacturer's share of committed supply (the number of doses it commits to supply annually divided by the annual target supply level of 200 million doses).

- When the total subsidy entitlement under a given Supply Agreement has been fully paid, GAVI and recipient countries continue to pay for, and the manufacturer continues to supply vaccines at the agreed price (at or below the tail price cap) until the manufacturer has supplied ten years’ worth of vaccine at the committed level. Vaccines supplied out of headroom (existing excess capacity) prior to dedicated capacity coming onstream count toward the ten year total commitment.

- After the full AMC subsidy has been paid out - toward ten-year supply commitments adding up to the 200 million annual dose level needed by 2020 - GAVI will remain responsible for ongoing tail price payments. Any amounts remaining in the AMC program, such as surplus investment income, would be directed toward other development uses by donors.

F. Expected Results

43. The pilot AMC is expected to yield high benefits, saving an estimated 7.7 million lives by 2030 with a much lower estimated cost per DALY saved (around $33) than the $100 benchmark cost for efficient health interventions in developing countries. AMC funds will help immunize 70 to 100 million infants, directly preventing between 900,000 deaths through 2020 during the AMC itself. In addition, the accelerated introduction of pneumococcal vaccines will prevent another 6.8 million deaths: by assuring a long-term sustainable supply and price, the AMC impact also goes beyond the contract period and beyond the specific children immunized as herd immunity expands the benefits of immunization to un-immunized children and older populations.

44. The AMC is designed to accelerate and foster: (1) research and development of new and second generation vaccines (via specific health efficacy requirements); (2) scale-up of dedicated production capacity (by offering assured funding in exchange for specific supply commitments); (3)
uptake by eligible countries (through low AMC price and low country co-payments); and (4) long-term sustainability (via low long-term, post-AMC tail prices and supply obligations). Expected results include:

- **Investment by the private sector in technologies for new and more efficient vaccine production and second generation technologies** tailored to developing country markets.

- **Investments by multinational market vaccine manufacturers in plant capacity** to meet the gradually increasing demand from low-income countries. The AMC will foster competition among manufacturers for the developing country market.

- **At least one emerging market vaccine manufacturer** moving a vaccine from early research and development through to product licensure in the next ten years.

- **Accelerated introduction of pneumococcal vaccines in a group of early adopter countries** beginning as early as 2009 (compared with historical delays of 15 years before new vaccines are introduced in poor countries).

- **Advance assurance to poor countries of a long-term price – the AMC tail price – that is predictable and sustainable.**

### III. Role of the Bank

#### A. Rationale for Bank Involvement

45. **The AMC pilot initiative fits the Bank’s poverty reduction and health objectives.** The Bank recognizes that improvements in health contribute not only to welfare, but also to income, especially in low-income countries,11 and to economic and social development.12 When cost is compared to health gains, immunization is among the most cost-effective of all health interventions.13 When cost is compared to additional income, immunization offers particularly high returns or benefit/cost ratios.

46. **IBRD’s role in providing the financial platform for the AMC is a demonstration of its leadership in innovative development finance and global public goods.** IBRD’s proposed role will make good use of its strong competencies in treasury services and management of donor-funded multilateral development initiatives. Establishing the AMC on IBRD’s balance sheet would respond to a specific request from shareholder donors, whose view is that IBRD’s direct financial support would maximize the financial efficiency, simplicity and credibility of the AMC.

47. **The Bank is also interested in testing the AMC concept through this pilot, and in the wider possibility of addressing well-defined market failures across a range of products** –

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including development and production of other needed vaccines and some drugs as well as possible uses in other sectors, such as for clean energy technologies.

B. Bank Support of Immunization and the AMC Concept

48. **The Bank has traditionally played a significant role supporting government actions to bolster national immunization programs in client countries.** To that end, the Bank has worked on strengthening the overall health delivery and financing systems, better enabling governments to introduce new vaccines or expand access to existing and available vaccines. The Bank works closely with WHO, which plays a key advisory and quality assurance role, and UNICEF, which provides vaccine procurement services to governments.

49. **As early as 1999, the Bank proposed an AMC-type structure to spur research and development, in the face of tremendous market uncertainty, in HIV/AIDS vaccines.** In 2004-2005, the Bank was a member of a task force, established by the Center for Global Development and sponsored by the Gates Foundation, that worked to develop the concept. In April 2005, the UK Government asked the Bank to convene a meeting of CEOs of vaccine companies, public-private partnerships, biotech firms, and G7 representatives to discuss the usefulness and feasibility of the AMC concept. As a result of that meeting and follow-on work, in June 2005 the G7 Finance Ministers asked Italy’s Finance Minister Tremonti to report back on the concept. Bank staff provided substantial support to the December 2005 Tremonti Report on AMCs.14

50. **At their meeting considering the Tremonti Report, G7 Finance Ministers supported a pilot AMC.** In January 2006, the Bank and GAVI were asked by the Italian and UK Governments to work on a pilot proposal for consideration by the Ministers. The proposal for a pilot AMC for pneumococcal vaccines was developed on the recommendations of an independent expert committee, and revised to reflect consultations with vaccine manufacturers and input from an advisory group of representatives of public-private partnerships for each candidate disease, WHO, UNICEF, industry, biotech, academia, and sponsoring governments. In February 2006, Italy, the United Kingdom, Canada, Russia, Norway and the Gates Foundation announced the $1.5 billion AMC pilot for pneumococcal vaccines.

C. Role of the Bank

51. **The Bank has been closely engaged in the development of the pilot AMC for over three years, providing support to donors and leadership on health, finance and legal aspects of its design and implementation.** From the outset, and consistent with the independent assessment of the best institutional arrangements to support an AMC, donor countries have anticipated that IBRD would provide the AMC’s financial platform.

52. **AMC Subsidy on IBRD’s balance sheet.** As proposed, IBRD would receive AMC donor grants directly as “restricted assets”, with a corresponding liability to pass on the funds to GAVI subject to the AMC terms and conditions. Thus, the AMC pilot is expected to operate on a pure pass-through basis, with IBRD simply passing on funds it receives as they are needed. To provide enhanced assurance, IBRD would make an additional commitment to pass on AMC funds even if they are not received on schedule from donors. Specifically, IBRD would commit to transfer funds to purchase AMC vaccines, upon specific requests from GAVI in accordance with the AMC terms and

conditions and the schedules of donor payments, whether or not donors actually pay on schedule. If demands are made for more than the amount of AMC funds already in hand, IBRD would pass on funds to GAVI only as and when it is scheduled to receive them, from donors.

53. Donors and manufacturers both expressed a strong preference for an intermediary entity to issue, and take responsibility for, the AMC offer. AMC donors believe strongly that the best placement for the AMC financial platform is on IBRD’s balance sheet. Donors want to avoid liability for direct suit by manufacturers, and manufacturers would prefer to avoid being in a position where recourse would be against governments that regulate them. However, establishing a new legal entity would be inefficient, costly, and have higher startup costs than other options that were considered, as well as potentially contributing to the unnecessary proliferation of vertical funds.

54. In examining different ways for IBRD to provide financial management of the AMC pilot, Management’s Finance Committee supported establishing the AMC as a pilot project on IBRD’s balance sheet. The options were evaluated against core criteria including market credibility (of greatest value to donors and manufacturers), efficient financial management, and financial and operational risks and costs. From the perspective of donors, manufacturers and the Bank itself, on-balance sheet intermediation by IBRD would be the most cost-effective way to establish market credibility and ensure that the AMC incentive is not unnecessarily discounted by manufacturers. AMC transactions would benefit from IBRD’s triple-A standing in the market and its existing network of counterparties.

55. The Bank would also provide standard financial management and administration services for the AMC program. This includes management of the AMC donor pledges, payments and inquiries, AMC liquidity and financial risks, commitments and disbursements, and related financial program management as well as legal, accounting, systems and reporting functions.

56. As with other innovative multilateral initiatives, this work will require close coordination across the Bank. CFP would manage the overall AMC program along with donor contributions, payments, commitments and disbursements; TRE would be responsible for investment management and hedging, with related accounting, systems and back office functions; LEG would be responsible for drafting and negotiating all framework agreements and providing ongoing legal support; ACT would handle accounting and accounting-based reporting responsibilities; HDN would be responsible for health aspects and representing the Bank’s views within the GAVI governance structure; CSR, FINCR, FINCF and others would provide support as needed. Bank staff would work closely with GAVI and the AMC Secretariat within GAVI, and collaborate on the provision of reporting and information to donors and AMC partners.

57. IBRD would charge the AMC program for its AMC-related administrative and financial management costs on a full-cost recovery basis. AMC staff time, hedging fees, external counsel costs, and other expenses would be tracked and charged annually to the AMC program.

58. In addition, IBRD would charge the AMC program for its balance sheet commitment based on IBRD loan terms. As such, a 30 basis point charge would apply annually to IBRD's outstanding exposure on grant payments owed from AMC donors. This charge is below that of market levels and reflects IBRD's nature as a shareholder cooperative, consistent with the development purpose of the AMC pilot and ultimate use of AMC funds. Over the life of the AMC, the total charge is estimated at $25.6 million ($22 million in current dollar terms). Both the charge on the balance
sheet commitment and administrative and financial costs\textsuperscript{15} are expected to be covered by investment income on AMC program balances.

59. The AMC would use IBRD’s capital to support a medium to long-term, financially innovative program tackling a global development problem. The use of capital is to fix a global market failure—underinvestment in and underproduction of vaccines needed in poor countries. The proposed pilot is consistent with the HNP health strategy, which calls on the Bank to help address market failures in health. The pilot also demonstrates the Bank’s leadership in innovative financing for development.

60. IBRD's Articles of Agreement do not make specific mention of IBRD's power to engage in this type of activity. The legal basis for providing this type of support is founded on the doctrine of implied powers which requires the activity to be in furtherance of IBRD's purposes and not prohibited by or inconsistent with its Articles of Agreement. \textbf{To approve the recommendations in this paper, Executive Directors would have to agree that supporting the AMC would be consistent with IBRD’s mandate.}

IV. Risks

A. Financial Risks

61. \textbf{Donor shortfall risk.} With the AMC on-balance sheet, the core financial risk to IBRD is the possibility of donor payment shortfalls due to default or delay.

\begin{itemize}
  \item \textbf{Payment delay risk}: Donor payment delay could potentially create a cash shortfall with respect to needed disbursements, or payment of the Bank’s fees.
  \item \textbf{Default risk}. Outright donor default would create a cash shortfall, likely requiring IBRD payout. Hedging donor credit risk for a tailored structure like the AMC using market instruments is most likely not possible. Several different approaches were explored, including insuring, guaranteeing or credit hedging donor payments using third party providers, but such instruments tended to be customized or illiquid when applied to the specific AMC structure, and would be complicated and costly to implement.
  \item \textbf{Substitution risk}. As a separate issue, it is possible that AMC donors might be current on AMC obligations – but at the expense of other financial obligations to the Bank such as to IDA.
\end{itemize}

62. \textbf{A number of factors mitigate these donor shortfall risks}. The payment schedules contemplated by donors provide reasonable assurance against payment delay risk, assuming there are no substantial accelerations to the expected disbursement schedule. Some donors expect to pay as funds are needed. Others will pay on an even annual schedule, while disbursements are expected to ramp up over the life of the AMC as recipient countries add the vaccine to their immunization programs one at a time. Overall, the expected payment schedules will create a limited liquidity cushion that will provide the AMC program with some capacity to cover payment delays, timing mismatches, or earlier than expected disbursement requests. (IBRD would not retain any remaining liquidity once all AMC obligations have been discharged.)

\textsuperscript{15} Full cost-based recovery of administrative and financial costs, charged annually to the AMC program, would take the place of the usual 25 basis point up-front fee on IBRD loans.
63. If a donor payment is delayed, IBRD is protected by the ability to agree on an adjusted payment schedule that would provide an equivalent NPV to the original schedule, plus the cost of related losses or adjustments resulting from the delayed payment (such as the cost of adjustments to cover swap agreement obligations related to the delayed payment). In addition, IBRD would continue to be paid for the outstanding exposure under its capital charge arrangements.

64. If a donor defaults on its payment obligations, in addition to the legal and financial protections in the AMC agreements, IBRD is indemnified individually by donors under the legally binding grant agreements. Donors are committed at the highest political levels to the pilot and five of the six donors are Bank shareholders. A donor default would carry reputational damage and would be met by collective political pressure from other donors.

65. In addition to its enforcement remedies in the grant agreements, IBRD has the right, in the event of non-compliance by a donor with its AMC financial obligations, to call a meeting of donors to determine an appropriate response, and to disclose the fact of non-compliance. Management’s intention is to ensure that donor default is a publicly disclosed event.

66. In the case of payment substitution risk, there are no specific protections across different legal obligations to pay IBRD. Senior management will need to pay close attention to payment obligations of AMC donors to ensure that there is not a substitution effect across other obligations to the World Bank Group.

67. Foreign exchange risk. AMC contributions will be made in EUR and USD. AMC disbursements are expected to be largely in USD, and the timing and amounts of cash outflows to purchase vaccines are uncertain. To avoid mismatches in the currency composition of inflows and outflows, it is expected that non-USD scheduled donor payments will be hedged into USD, consistent with the largely USD basis for the vaccine market in developing countries. However, with the recent market turmoil and volatility in foreign exchange rates, consideration may be given to making the AMC offer partly in USD and partly in EUR.

68. Litigation risk. The AMC legal agreements seek to delineate IBRD’s limited role and obligations and to limit supplier rights only to funds owed to IBRD by donors, and only for vaccine purchase. In addition, each AMC manufacturer must formally acknowledge and accept the AMC terms and conditions – including explicit acceptance of IBRD’s limited obligations – as a precondition to eligibility for AMC funding. Even with these provisions, however, there is a risk that IBRD (and/or GAVI and donors) could be subject to suit. IBRD retains a certain level of protection given its core mandate, and industry experts believe that manufacturers would think twice about negative publicity associated with suing IBRD and potentially diverting funds from needed vaccine purchases. GAVI and UNICEF experience to date also indicates that litigation is very unusual in the context of vaccine sales to poor developing countries.

69. Financial risks may also arise from related operational or partnership risks. One area of concern relates to whether non-financial risks – for example highly visible vaccine-related injuries or deaths, or a corruption issue in which GAVI is closely associated – could result in donor willingness to stop AMC payments. This possibility is mitigated by the terms of the legal agreements, which specify the rare catastrophic circumstances under which the AMC can be suspended or cancelled with respect to a particular vaccine or as a whole. In those circumstances, donors could be entitled to stop payments; IBRD would also be entitled to stop payments under the same circumstances. Legal provision is also made for a possible successor to GAVI to assume its responsibilities should it go out of business (or out of the immunization business).
B. Operational Risks

70. **Risk of failure/AMC design.** The AMC is a market intervention in a market subject to both supply and demand risk, with limited competition, asymmetric information, and indivisibilities in capital investment. **It will fail if key manufacturers do not participate, or if countries do not demand target vaccines.** And if it succeeds, it is likely to be subject to criticism that it provides unnecessary profits to pharmaceutical firms.

71. To minimize these risks, extensive work has gone into pilot design. Key terms, and the model used to set key AMC parameters, have been widely vetted by developed and developing country manufacturers, public-private partnerships, recipient countries, academics, international institutions and expert committees. (See Annex 1 for a summary of the AMC design and consultation process.) The AMC agreements mandate continuing work to improve demand data, including soliciting expressions of interest by GAVI client countries and reviewing estimated demand by country, and a monitoring and evaluation framework is being put in place. If necessary, or in response to unexpected changes such as regulatory changes that increase a vaccine’s cost structure, AMC terms may be adjusted by the Independent Assessment Committee on the advice of an appropriately constituted expert group to make the AMC more generous and increase the incentive effect. **Overall, Bank management supports the AMC “package”, and believes that the possibility of very high health and vaccine market benefits justifies taking the risk of project failure through non-participation as well as the risk of public criticism over economic profits that should accrue to participating manufacturers except for the least efficient producer.**

72. **Tail price.** To set the most appropriate tail price cap, the AMC expert groups focused extensively on balancing a set of factors. The tail price is critical to ensure value cap for the taxpayer funds providing the AMC subsidy. However, perfect price-setting is difficult. With only two vaccine suppliers expected to have pneumococcal vaccines on the market in the early years, the AMC price needs to be set high enough so that the less efficient producer can cover its variable costs and has an incentive to participate. The overall price should also take into account residual demand uncertainty, and possible differences in applied discount rates. The capital subsidy must be roughly sufficient to cover capital costs of the least efficient producer. **Success of the AMC hinges on the participation of this second producer, which is needed to create and meet market demand until a third, emerging market supplier enters the market.**

73. The tail price should therefore be capped at a level equal to or somewhat higher than the second producer’s variable cost. Because estimates of variable cost are subject to much uncertainty, and cost information is closely held by the industry, studies were conducted over the last 2-3 years to establish ranges of cost of goods sold (COGS) for conjugate pneumococcal vaccines, which resulted in estimates of COGS of just over $3.00.

74. After considerable deliberation on all of these points, a tail price cap of $3.50 was set. With little public information available in setting the price, the conclusion by the Bank and AMC donors is that the price is within a reasonable range necessary to make the AMC successful. At the same time, the Bank and donors should be prepared for criticism from both the vaccine industry and the public that this pricing is respectively too low or too high. This actual and potential criticism is managed under the AMC communications strategy, led by GAVI and supported by the Bank, which tracks and responds to expected and actual publicity about the AMC.

75. **Demand risk.** Success of the AMC pilot depends on the participation both of GAVI countries and the vaccine industry. Managing these two interdependent variables is critical. Industry may be reluctant to engage as long as it has concerns about whether demand will fully
materialize. Conversely, country demand is a function of available vaccine funding and prioritization of pneumococcal disease in a country’s national health program.

76. **Risk of insufficient country demand.** A number of actions support countries interested in receiving AMC-subsidized vaccines. Country ownership is a first step: interested GAVI-eligible countries have to determine that providing pneumococcal vaccines is a national health priority, and undertake to provide a co-payment ($0.10 to $0.30 per dose purchased depending on country income levels). GAVI’s top-up of the country co-payment addresses country concerns about availability of vaccine funding, mitigating country financial risk relating to the country co-payment obligation. WHO plays a role in ensuring that the information about pneumococcal disease burden and vaccine value reaches key decision-makers in-country. AMC technical partners, including WHO, the AMC Secretariat at GAVI, pneumoADIP and its successor AVI, continue to refine data about developing country demand. **Regular reviews of estimated demand, aggregated country by country, will be conducted during the AMC by GAVI and UNICEF.** The level of vaccine industry participation is expected to increase once it is evident that donor and GAVI funding is certain and demand is predictable.

77. **Risk of non-participation by industry.** Manufacturers must make a binding commitment to a supply quantity to be eligible for AMC pilot funding, but firms are cautious. This is in part due to the perception that the international health community has historically overestimated demand in developing countries, confusing it with need. Manufacturers are also concerned about GAVI’s extensive and long-term funding commitments to the AMC. Firms may derive greater profits if they delay introducing new vaccines into lower-priced markets, and/or may view AMC risks as uneconomic or unacceptable.

78. **To minimize these risks, consultations were held, and continue to be held, with developed and developing country manufacturers to ensure effective AMC design.** These consultations over the lengthy AMC development process have to some degree involved manufacturers in the AMC’s success or failure. Given the public visibility of the AMC initiative and known participation by manufacturers in consultations ultimately, if manufacturers do not participate, the AMC terms may be changed by the Independent Assessment Committee to increase the incentive effect.

79. A separate and distinct risk that may affect participation by manufacturers relates to the purchase of pneumo vaccines by the Pan American Health Organization (PAHO). PAHO’s tender terms contain a provision that its suppliers may not offer lower priced vaccines to other purchasers without offering the same price to PAHO. As stated, the provision would preclude manufacturers from participating in the AMC and at the same time selling AMC-eligible vaccines to PAHO for middle-income developing countries at higher prices. The Bank and GAVI are part of a working group with a mandate to resolve this issue.

C. **Reputational Risks**

80. **As with any highly visible development effort, the Bank faces reputational risks** with the public and with the spectrum of AMC stakeholders (donors, recipient countries, pharmaceutical, vaccine and biotech firms, market counterparties, GAVI, public international health agencies including WHO and UNICEF). The AMC is a well-publicized initiative, having been taken up initially by the

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16 The pneumoADIP is the Accelerated Development and Introduction Program for pneumococcal vaccines, and AVI is the Accelerated Vaccine Introduction initiative.

17 Strategic forecasts will be done two to three times each year and will coincide with GAVI’s country application cycles. Supply chain forecasts will be done on a rolling basis for the next 12-24 months and form the basis for firm order timing.
G7 Finance Ministers. The Bank has had substantial input into the design and implementation of the AMC structure, and has publicly supported the concept.

81. **If the AMC fails to produce its expected results, the Bank will be associated with that failure.** Indeed, some Civil Society Organizations (CSOs) have already questioned the efficacy of the AMC model. They claim that the AMC price is much higher than a vaccine producer’s COGS and will generate windfall profits. They also claim that better results could be obtained by using the donor-funded $1.5 billion on a long-term procurement contract with UNICEF. Managing the risk relating to these unsupported CSO claims has been an ongoing effort throughout the AMC design process, and will continue. The design of the AMC has been repeatedly vetted in a number of forums (including CSOs) over the last few years, resulting in structural enhancements which are reflected in the final terms. After the launch of the AMC, CSO outreach and communication will remain a core focus of the AMC communications strategy led by GAVI and supported by the Bank.

82. **Risk of vaccine-related catastrophe.** In the event of vaccine-related death or injury, vaccine procurement scandal, the diversion of AMC funds to corrupt use, or other similar occurrences, the AMC could be undermined, and the Bank could share in the resulting reputational damage. Although the legal agreements will limit IBRD’s liability, it has little direct control over such risks. Mitigation of this risk rests primarily on the extensive quality control measures inherent in the international vaccine approval processes and the AMC structure. Before being approved for AMC support, vaccines must both be approved by appropriate regulatory control authorities, and clear the WHO prequalification process. The AMC will be closely monitored, including by the Independent Assessment Committee, and reporting and monitoring obligations will be specified in the framework agreements on progress by manufacturers and developing countries, and in operational areas handled by GAVI. These reporting obligations will help keep the Bank focused on performance and risks within its responsibilities, and ensure that the Bank is aware of operational progress and shortfalls outside its areas of control.

83. **Partnership/Implementation Risk.** The AMC pilot would create another close working relationship between the Bank and GAVI. The Bank was a driving force in the establishment of GAVI, and has been an active member of the GAVI Alliance Board. The Bank’s partnership with GAVI has multiple aspects, from working together on immunization-related work and through several trust funds, to IBRD’s role as Treasury Manager for the International Finance Facility for Immunisation, which funds GAVI’s work, and IFFIm may fund a part of GAVI’s AMC obligations in the near-to-medium term.

84. **A key element of the AMC’s success will be GAVI’s role in its implementation.** The AMC offer to industry will be extended jointly by GAVI and IBRD. GAVI advises countries on their immunization programs, coordinates across the partners of the alliance, and funds vaccine programs through its country application process. It is responsible for periodically updating the demand forecast that shapes supply commitments, and contracts with UNICEF to procure vaccines. GAVI will act as the secretariat to the AMC and to the Independent Assessment Committee that is responsible for final approval of candidate vaccines and decisions affecting AMC terms.

85. In addition to its operational support, GAVI has a very large financial role in the AMC. **Through 2030, GAVI will provide up to $7.5 billion in AMC funding above and beyond the subsidy provided by the AMC donors.** GAVI’s Board has specifically approved funding for the AMC of $1.3 billion, the amount expected to be needed through 2015. AMC funding from GAVI beyond that amount remains subject to GAVI Board approval, which in turn will depend on funds being available. GAVI’s donors include Australia, the Bill & Melinda Gates Foundation, Canada, Denmark, the European Commission, Denmark, Germany, Ireland, Luxembourg, The Netherlands,
Norway, Sweden, United Kingdom, United States, and private contributors. There is significant overlap between GAVI donors and AMC donors, as well as some overlap with IFFIm donors.Withdrawal by any one of the key donors (Canada, Italy, Norway, the United Kingdom and the Bill & Melinda Gates Foundation) would impact both parts of the AMC’s funding – that is, both the subsidy and the long-term tail price. The Bank could share the reputational impact if there are AMC operational or funding shortfalls on GAVI’s side.

86. The Bank must closely manage its important partnership relationship with GAVI. The Bank has a seat on GAVI’s Board (along with representatives of donor and recipient countries, industry, WHO, UNICEF, the Bill & Melinda Gates Foundation, and private individuals). The Bank will share two seats on the ten-member Executive Committee with WHO and UNICEF, and is expected to maintain seats on GAVI’s Programme/Policy and Finance/Audit Committees. The AMC legal agreements will limit IBRD’s liability to manufacturers if there are failures or problems arising from GAVI. There are specified reporting and tracking obligations, and there will be annual meetings of the AMC Stakeholders Committee (donors, GAVI and IBRD). In addition, IBRD is represented on the five-member IAC selection and oversight panel that is responsible for selection, appointment and removal of IAC members. And on an ongoing basis, the Bank must take full advantage of its roles in GAVI, and be an active, engaged member of the GAVI governance structures on which it sits.

V. Conclusion and Recommendations

87. The AMC is a complex mechanism, with an array of associated risks. It is nonetheless a carefully designed and important pilot. It was structured with the benefit of lengthy consultation and input from a wide range of actors with extensive and varied expertise: developing countries and sponsoring governments, vaccine manufacturers and biotech firms, economists, academics, pediatricians, international financial, health and development institutions, CSOs, public-private partnerships, as well as experts in law, public health, immunization policy and management, and vaccine production. The pilot is a market-based incentive mechanism, priced to provide a subsidy designed to support a transition from developed country market-level prices to a COGS-based price, providing the best possibility for long-term, sustainable take-up by developing countries.

88. The AMC pilot and its design process were recently validated, through an extensive six-month inquiry, by the United Kingdom’s All-Party Parliamentary Group (APPG) on Pneumococcal Disease Prevention in the Developing World. The APPG inquiry focused on the global disease burden of pneumococcal disease and pneumonia, and the interventions available to prevent and treat it. The APPG Report found “convincing evidence that pneumococcal disease is a serious, preventable cause of death and disability in need of urgent action.” The APPG reached a positive conclusion: “the AMC should accelerate the availability of affordable, effective pneumococcal vaccines to the world’s poorest countries in a sustainable manner. Indeed, we could not envisage a more appropriate or practical system capable of providing an adequate supply of affordable vaccine.”

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18 Norway and the United Kingdom contribute directly to GAVI, IFFIm and the AMC; Canada and the Bill & Melinda Gates Foundation contribution both to GAVI and the AMC. IFFIm-only donors include France, South Africa and Spain; Russia will contribute only to the AMC.

89. **Management recommends that Executive Directors approve:**

1. IBRD agreeing to provide the financial platform supporting the pilot AMC for pneumococcal vaccines, consistent with its purposes under the Articles of Agreement;

2. placing the $1.5 billion AMC subsidy on IBRD’s balance sheet, accepting donor grants as restricted assets subject to the AMC terms and conditions with a corresponding liability to pass through scheduled donor payments as needed for vaccine purchases;

3. charging the AMC program:
   - on a full-cost-recovery basis for administrative and financial management services; and
   - a 30 basis point annual balance sheet commitment charge on outstanding exposure on AMC donor grants.
### ANNEX 1: AMC CASH FLOWS SUMMARY

#### AMC Cash Flows Summary

**Illustrative Base Scenario**

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ANNEX 2: AMC DESIGN AND CONSULTATION PROCESS

The development of the AMC and the pilot for vaccines against pneumococcal diseases has benefited from extensive consultations with, input from, and decisions of expert groups with a wide range of appropriate skills and expertise.

- A working group led by the Center for Global Development developed and assessed the concept (2003 to Spring 2005).

- At the Spring Meetings in 2005, the Bank was asked to convene a meeting for the G7 sous-sherpas with vaccine manufacturers, which led to the AMC being taken up by the G7 Finance Ministers in June 2005.

- The Italian Government, supported by the Bank, presented the Tremonti Report on the AMC concept based on detailed modeling, industry consultations, and advisory group input from public-private partnerships, vaccine and legal experts, economists, and other stakeholders. (December 2005)

- An independent expert committee, chaired by the Malawi Minister of Health, evaluated candidate diseases (including HIV/AIDS, tuberculosis, malaria, rotavirus and human papilloma virus) and concluded that pneumococcal diseases were the most suitable candidate for a demonstration AMC.

- Industry consultations were undertaken in several rounds from 2005 through 2008, resulting in adjustments to the AMC structure to enhance its impact on private sector decision-making. The AMC team has consulted with manufacturers with active or pipeline pneumococcal conjugate vaccine programs, including the multinationals Wyeth, Merck, Sanofi Pasteur, GlaxoSmithKline Biologicals, and Novartis, and emerging manufacturers Biological Evans, Shanta Biotechnics, Serum Institute of India and Panacea (India), Chengdu Institute of Biological Products (China), and BioManguinhos/Fiocruz (Brazil).

- Developing country consultations with health policy makers, pediatricians, researchers, immunization managers and other developing country experts were conducted with a focus on participation in the Advisory Group and Expert Committee (2005-2008).

- Development of specific health efficacy requirements for the target vaccine was undertaken by an expert group convened by WHO; its recommendations were considered and approved by WHO’s Strategic Advisory Group of Experts (SAGE) and the final target product profile will be approved by the Independent Assessment Committee. (Spring to Fall 2007)

- Review of the AMC structure and model was undertaken by an Economic Expert Group, and final recommendations on terms by a follow-on Implementation Working Group. (Summer 2007-Summer 2008).
ANNEX 3: LEGAL STRUCTURE

The AMC will be established through a suite of legal agreements; no new legal entity will be created. These framework agreements will set out the AMC’s key terms, including legal obligations of donors and the implementation details for the structure. The framework agreements will specify the market size of the AMC, TPP requirements for the target vaccine, the AMC subsidy, tail price cap, demand guarantee and supply commitment arrangements. They will establish and delineate the responsibilities and processes of the Independent Assessment Committee, as well as the roles of IBRD and GAVI.

Once the establishing agreements are signed, donors will begin to make payments into the AMC according to their preset schedules or according to demand, as applicable; GAVI and the Bank will put in place the AMC support structures; and the development and scale-up of pneumococcal vaccines to meet AMC goals will be monitored. When a manufacturer produces a candidate vaccine, it will be evaluated by the Independent Assessment Committee with expert assistance and in coordination with WHO’s pre-qualification process. Upon approval, the manufacturer can enter into a supply agreement consistent with the AMC terms and conditions. The transactions associated with the procurement and delivery of vaccines to countries and payments to manufacturers will be supported primarily by GAVI and UNICEF.

The specific legal agreements will include:

1. AMC Terms and Conditions (specifies the core AMC terms, and will be attached to other AMC legal documents)
2. Stakeholders Agreement (between donors, GAVI and IBRD)
3. Offer Agreement between IBRD and GAVI (establishing the AMC offer to industry)
4. pro forma Supply Agreement (between AMC manufacturer and UNICEF as procurement agent, attached to the AMC Offer Agreement)
5. Donor Grant Agreements (assets underpinning the AMC offer)
6. AMC Registered Manufacturer Agreement (required terms for a manufacturer to apply for AMC funding)
7. IAC Charter and Procedural Bylaws (regulating the functions of the Independent Assessment Committee)
8. Master Definitions Agreement
Offer Agreement between GAVI and the Bank

- Key purpose is to set out the offer to vaccine manufacturers as well as the undertaking from GAVI to enter into Supply Agreements
- Includes undertakings between GAVI and the Bank with respect to disbursement of funds and day-to-day management of the AMC process
- AMC Terms and Conditions will be attached as a schedule

Stakeholders Agreement

Parties will be the Bank, GAVI, donors (Grantors), sets out the mechanics in relation to matters relevant to all Grantors, including:

- Several liability of Grantors for their Grant Payments
- Usage and application of AMC funds
- Undertakings from GAVI and IBRD relating to their obligations under the legal agreements
- Arrangements with respect to use of funds left over at end of AMC
- Change in circumstance events and enumerated events which can lead to early winding down of the AMC
- Changes to Grant Payment Schedules; consequences of Grantor late or non-payment

AMC Terms and Conditions

Not signed by parties but attached to the Offer Agreement, setting out the provisions that vaccine manufacturers need to know in order to understand the AMC offer, including:

- AMC offer/subsidy amount
- Vaccine purchase price (the AMC subsidy plus tail price)
- GAVI’s co-payment arrangements
- IAC inflation review
- Details relating to IAC functions
- Conditions to eligibility for manufacturers to receive AMC subsidy
- Target Product Profile
- Circumstances surrounding entry into Supply Agreement (pro forma Supply Agreement attached as a schedule)
- Ongoing industry consultation arrangements
- Change in circumstance events or other events that could lead to wind down of AMC prior to its planned end