

Q&A: Advance Market Commitments (AMCs)

Q: What is an AMC?

A: An Advance Market Commitment (AMC) 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.

An Advance Market Commitment (AMC) is a financial commitment to subsidise the future purchase of a vaccine not yet available if an appropriate vaccine is developed and if it is demanded by the poorest developing countries. An AMC is not a purchase guarantee, as industry will only receive the subsidised price if the product meets targeted standards, if countries demand the product, and if an affordable, long-term price can be negotiated with the individual vaccine manufacturers.

Q: Why are AMCs needed?

A: Communicable diseases are the world's biggest killers of children and among the top causes of death for adults in the developing world, with the poor suffering disproportionately. While efforts to increase access to immunisation have undoubtedly saved lives, gaps in coverage and vaccine availability remain. Every year, 3 million people die from diseases that could have been prevented by vaccines.

A number of new vaccines will soon be available that could prevent many of these deaths. However, it currently takes an average of 15-20 years for a new vaccine to become widely available at affordable prices in the developing world. An Advance Market Commitment is a results-based and market-driven mechanism that seeks to address this problem by accelerating the introduction of appropriate vaccines in impoverished countries.

By creating markets for vaccines for developing nations comparable to markets in wealthier countries, Advance Market Commitments are a bold step toward erasing the health inequities between rich and poor.

Q: Why is a pilot necessary?

A: A pilot AMC has been designed for pneumococcal vaccines to demonstrate both the feasibility of the AMC mechanism and its impact on accelerating vaccine development, production scale-up and introduction.

Once established, the Pneumococcal AMC will, through the support of industry and governments, help to prevent unnecessary pneumococcal deaths in the poorest countries of the world. Importantly, it will also enable stakeholders to

quickly assess the impact of the AMC mechanism to determine if AMCs will be able to accelerate other health priorities such as vaccines against malaria.

Q: What is pneumococcal disease?

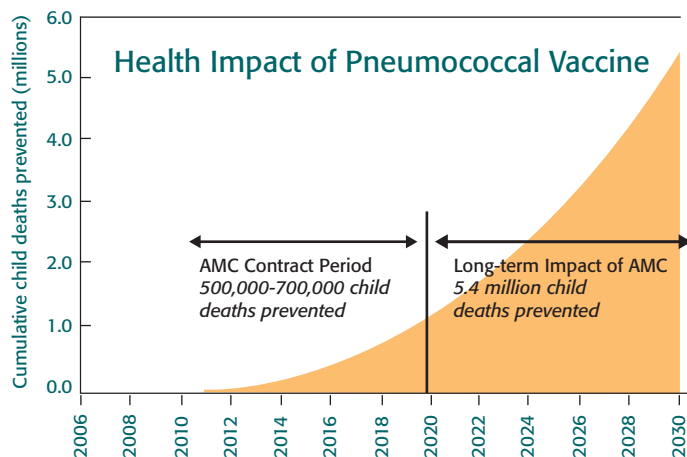
A: Pneumonia is the leading infectious cause of child mortality worldwide, causing an estimated 1.9 million (or 19%) of the estimated 10 million child deaths that occur each year. Pneumococcal disease is the leading cause of these child pneumonia deaths, as well as the second leading cause of childhood meningitis deaths. It kills more than 1.6 million people including 700,000 to 1 million children under age 5 every year.

Pneumococcal disease is a growing and increasingly urgent global problem. 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.

Q: How many children will be immunised and how many deaths will be prevented by pneumococcal AMC?

A: The pilot AMC is expected to result in 70 to 100 million immunised infants over the life of the AMC. This will prevent 500,000-700,000 deaths during the AMC itself. However, the impact of the AMC goes beyond the contract period as it assures a long-term sustainable supply and price. The impact also goes beyond the children immunised, as herd immunity will act as a multiplier, expanding the benefits of immunisation to un-immunised children and older populations.

Potential deaths prevented by accelerating the adoption of pneumococcal vaccines into developing countries



Q: What is the cost of the pneumococcal pilot AMC?

A: The recommended size of the donor contribution to the AMC is \$1.5 billion in nominal terms.

Q: What is the timeline for a pilot AMC?

A: The Pneumococcal AMC Pilot will be established and implemented over a 13-year period from 2007 to 2020, moving through several different phases in the project's life. The first payments are anticipated to begin in 2010 and last for 9 to 10 years.

Q: When will a pneumococcal vaccine for the developing world be available?

A: The pneumococcal vaccine pipeline includes one licensed product and more than 20 candidate vaccines in varying stages of development. Two vaccines that extend protection for populations in both developing and industrial countries by adding more serotypes may be licensed by 2010. Other vaccines, including those from emerging manufacturers may come to the market in the following five to ten years.

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Q: Why can't developing countries use the same pneumococcal vaccine as industrialised countries?

A: The one licensed pneumococcal conjugate vaccine is registered in over 75 countries and has safely vaccinated more than 30 million children in industrialised countries. Although this vaccine is safe, and highly efficacious, it lacks two serotypes that are important in many developing countries, and therefore its impact on health will be more limited than an ideal vaccine.

Just as important, there is not enough of the current vaccine to meet the needs of the developing world. The current vaccine supply was sized to meet a specific level of demand and capacity is completely insufficient to meet the expected growth in demand from developing countries.

Q: How will poor countries afford these vaccines when the AMC ends?

A: The post-AMC supply and price of pneumococcal vaccines are as important as the availability of the vaccine during the AMC period. Two components of the AMC arrangement will ensure sustainability:

1. Each vaccine manufacturer that agrees to participate in the AMC program will be required to set and commit

to a post-AMC price for the vaccine at the time that it qualifies for AMC funding;

2. When vaccine makers sign the Supply Agreement, they are committing to meet post-AMC supply demands as needed.

Q: Who will be responsible for the implementation of a pilot AMC?

A: The GAVI Alliance and the World Bank would be the two entities directly responsible for supporting the programmatic and financial functions of the AMC based on their relative strengths.

In addition to the two primary implementing entities, stakeholders such as donors, pharmaceutical, vaccine and biotech firms, developing countries, and technical agencies such as WHO and UNICEF will be critical in the implementation and success of an AMC.

Finally, the Independent Assessment Committee (IAC) is the cornerstone of the proposed AMC. This committee will oversee core parts of the AMC process, including the establishment of Target Product Profiles (TPPs) for candidate vaccines and ascertaining whether they are met. The credibility of AMCs rests largely on the perception of industry, donors, and developing country governments about the independence, fairness, and reliability of the IAC.

Q: What other measures are needed to ensure the pneumococcal vaccine is successfully adopted by developing countries?

A: As part of its activities to accelerate access to vaccines and to strengthen immunisation, GAVI and a variety of donors and technical partners are considering increased investments to strengthen vaccine introduction. In the case of GAVI, activities such as the following are either already underway or will be evaluated and potentially implemented by GAVI and its partners including WHO, UNICEF, the PneumoADIP, and others:

1. Complementary funding to strengthen national delivery systems;
2. PneumoADIP and others to aid governments to make timely, evidence-based decisions on pneumococcal vaccine introduction;
3. GAVI and partners improving the transparency of forecasting systems;
4. GAVI and partners improving the accuracy of forecasting through analysis to understand bottlenecks;
5. Explore mechanisms such as Letters of Intent to allow governments to indicate their interest in a new vaccine in a more timely fashion;
6. Explore public sector providing a take/or pay guarantee for a small amount of initial volume to share the demand risk.