



**ADVANCE  
MARKET  
COMMITMENTS**  
*for vaccines*



Pneumococcal AMC:

# Frequently Asked Questions

## **Why do we need Advance Market Commitments?**

Immunisation is a proven tool to prevent infectious diseases, yet vaccines are not available to children in all countries. We need to create a new dynamic way to accelerate the development, manufacture and introduction of new vaccines for the world's poorest countries.

## **Why are new vaccines needed?**

For some of the diseases that cause the greatest burden of sickness and death in developing countries, such as malaria, tuberculosis and AIDS, vaccines have not yet been developed. For other diseases, many safe and effective vaccines already exist, but some of these need to be tailored for developing countries. They may need to be adapted to resist extreme temperatures or to protect against a particular disease strain that is common in a given region.

Advance Market Commitments (AMCs) incentivise companies to invest in manufacturing and supplying new vaccines, and in developing future vaccines.

## **Why not spend the money on treatment rather than vaccines?**

Vaccines are designed to prevent disease, whereas medicines provide treatment. While both are important, there are many good reasons to invest in prevention. Any parent would prefer that their child stays healthy, rather than fall sick and need treatment. Prevention means avoiding suffering, and is often cheaper for the individual and for the health system. For infectious diseases, vaccines are the most cost-effective form of prevention. Even where effective drugs exist, treatment is not always as straightforward as it sounds. In many places, especially poorer countries, sick people cannot always reach a hospital or doctor. Even if they do, diagnosis is not always accurate, and the right drugs might not be available or might be too expensive. For some diseases, such as malaria and tuberculosis, drug resistance is making treatment less effective.

## **Why not spend the money now to buy existing vaccines?**

The AMC has been designed to accelerate the development and manufacture of vaccines that do not yet exist. The AMC addresses this issue by establishing prices before the vaccine has been developed and productive capacity has been built. While an AMC is an innovative and attractive model for combating infectious diseases, no one solution can ever provide all the answers to global health problems. Other measures are still needed, such as providing conventional grants for research, helping governments set up and sustain immunisation programmes, ensuring the development of treatment drugs, and strengthening health services and systems. AMCs will complement, not replace, these strategies.

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**“Every child must be reached,  
because every child counts”**

Former Secretary of State Madeleine Albright

### **How do AMC's stimulate the development of vaccines for developing countries?**

Given that developing countries often have little ability to pay, manufacturers give priority to providing vaccines for industrialised markets where their investments can be recouped more quickly.

AMCs for vaccines provide the prospect of sustainable markets in developing countries and initial sales prices that allow vaccine makers to recover their original investment. An AMC gives developing countries the purchase power to buy the needed vaccines.

### **Who benefits most from an AMC?**

Children in developing countries are the big winners. They are currently at risk of dying from a range of diseases that could be prevented if safe, effective vaccines were available to them at affordable prices. Their parents, their communities, and society as a whole will share the benefits of this initiative.

Vaccine makers will take the initial risk of developing new vaccines, and establishing manufacturing facilities. In order to be eligible to have their vaccines sold through an AMC, vaccine makers will have to produce appropriate vaccines in sufficient quantities, and agree on pricing, both during the AMC funding period and beyond. The money that companies will earn from selling their new vaccines to developing countries at the AMC price will enable them to recoup initial investment

### **Why is a pilot necessary?**

A pilot AMC will demonstrate both the feasibility of the AMC mechanism and its impact on accelerating vaccine development, investment in production capacity and introduction of the resulting vaccines in developing countries. Through the pilot, practical concerns about how to establish appropriate legal and financial structures will also be addressed, streamlining similar ventures for other diseases in future.

### **What are pneumococcal diseases and what is their impact?**

Serious pneumococcal diseases – primarily pneumonia and meningitis – are the leading vaccine-preventable cause of death in children under five years old. The World Health Organization estimates more than 800,000 children in this age group die every year from pneumococcal infections. Although children everywhere are affected, more than 90% of these deaths occur in the developing world.

Further, interrelationships with other conditions are making pneumococcal disease a growing and urgent global health issue. Children infected with HIV are especially vulnerable to serious pneumococcal infections like pneumonia and meningitis. In fact, they are up to 40 times more likely to become ill than other children. And once they are sick, HIV-positive children are far more likely to die from pneumococcal disease, especially when, as is frequently the case in developing countries, they are not getting appropriate AIDS medication.

Pneumococcal diseases hit poor families the hardest. Paying the hospital bills for a sick child may require them to use precious savings or to borrow money, and parents are deprived of income while they feed and care for their hospitalized children in countries where nursing care is limited.



In addition to the deaths caused, pneumococcal disease disables many survivors. For example, life-long disabilities that often occur after pneumococcal meningitis include hearing loss, learning delays, speech impediments and paralysis. These disabilities in turn can mean fewer educational opportunities and poor employment prospects, contributing to a vicious cycle of poverty and ill health.

### Why does the pilot AMC address pneumococcal diseases?

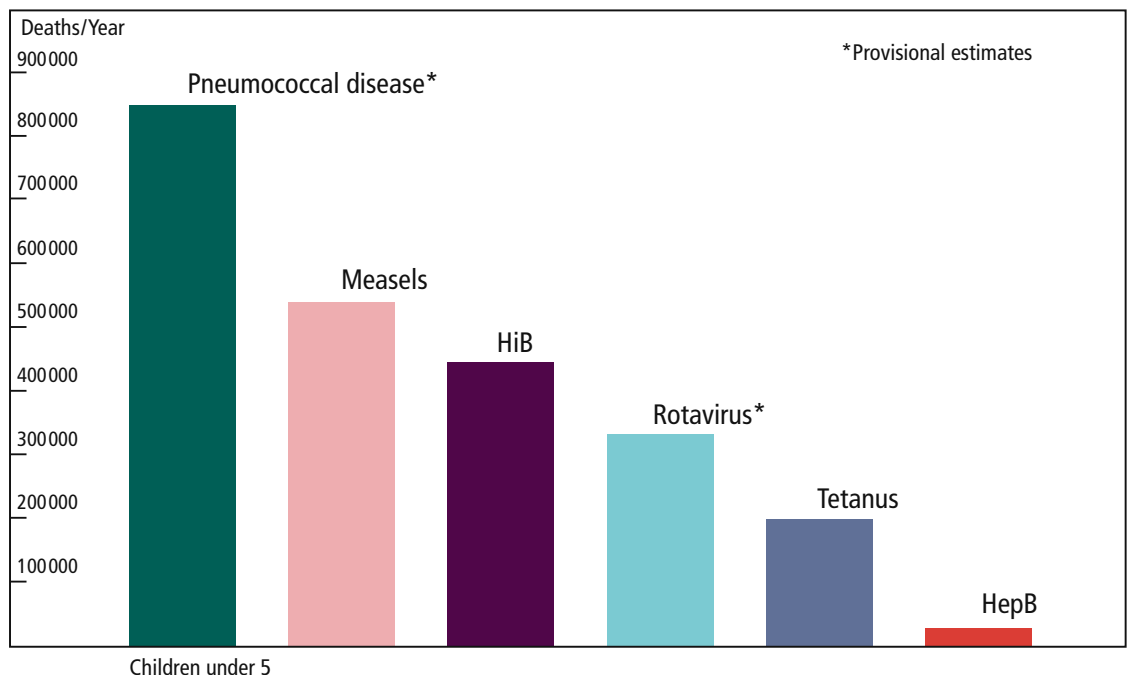
The decision about which disease to target was made by an independent expert committee chaired by Dr. Hetherwick Ntaba, former Minister of Health, Malawi. The committee included members from both developing and industrial countries with expertise in public health, epidemiology, industry economics, vaccine development and law.

The committee came to the conclusion that of the six diseases they examined, pneumococcal vaccines were the best choice for a pilot AMC because of the potential to quickly demonstrate that the AMC concept works and because of the likely positive impact on the health of people in developing countries.

## Pneumococcal vaccines are the right choice for the pilot AMC because:

- In the case of pneumococcal vaccines it is economics, not science that currently stands in the way of new vaccines reaching developing countries. Various companies have suitable vaccines in the late stages of development and the AMC will provide the motivation for them to accelerate the process of making them available.
- Success can be easily measured – it will be defined by industry's willingness to build manufacturing capacity that would not otherwise have been developed. This is expected to happen quickly, yielding results in the near future that will drive decision-making about possible AMCs for other diseases.
- This AMC represents good value for money. Because there is a large global market for pneumococcal vaccines, the pilot AMC will leverage the investments that industry has already made in research and development that were driven by the markets in high- and middle-income countries.
- This AMC will only pay for the incremental investment needed to supply developing countries.

### Leading Cause of Vaccine Preventable Death in Children under 5 Years old



### **Why is a new vaccine against pneumococcal disease needed?**

While a vaccine for pneumococcal disease exists and is widely used in Europe and the United States, it is not optimal for developing countries. This is because there are many different strains of pneumococcal bacteria, known as serotypes. The current pneumococcal vaccine protects against seven serotypes (7-valent). In developing countries other serotypes, in addition to those covered by the 7-valent vaccine, are common, so a vaccine providing broader coverage, including these additional serotypes is needed.

The current vaccines are also too expensive and not available in sufficient quantities to meet the potential global needs if all countries start immunising their children.

### **What new pneumococcal vaccines are currently in development?**

Developing countries need a pneumococcal vaccine that is safe and effective against the prevalent disease strains, can be delivered as part of existing vaccine programmes and comes in a form that is easily adapted to local conditions.

More than twenty conjugate vaccines as well as common protein vaccine formulations are in the early stages of development. Several of these products may be licensed between 2015 and 2019. Potential emerging market suppliers for conjugate vaccines include producers in Brazil, Cuba, India and China who may manufacture their own vaccines or be licensed by a multinational to produce an existing vaccine.

Two late-stage vaccine candidates with adequate serotype coverage are currently in development: a 10-valent vaccine and a 13-valent vaccine. Both these vaccines may meet the needs of developing countries and are likely to be available by late 2009.

Several multinational companies have discontinued work on their pneumococcal vaccines but could potentially resume their efforts. A few "common protein" vaccines, which would protect against all serotypes, are in development.

### **Will there be other AMCs?**

Advance Market Commitments could be developed for other diseases, such as malaria, tuberculosis and AIDS. The lessons learned from the pilot AMC for pneumococcal disease would be applied to new AMCs. The experience gained in how best to set up the economic structure, the process for establishing the scientific standards for the vaccine through a Target Product Profile (TPP), the governance structure, and the legal and regulatory agreements would all be useful blueprints. Each new AMC would involve a thorough technical analysis of the scientific, economic and public health issues.



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