

Creating markets to save lives

Vaccines are a proven tool to prevent infectious diseases, and childhood immunisation is one of the great success stories in global health. **Vaccines save and protect lives.**

Although many diseases are under control thanks to vaccination, there are still some deadly diseases, which primarily affect poor countries, for which vaccines are not optimal or do not yet exist. And there is little incentive for pharmaceutical companies to develop them. Moreover, many existing vaccines are not available in the right quantities to meet the large demand from developing countries.

Therefore, children around the globe continue to get sick and die from vaccine-preventable diseases every day. Millions of young lives could be saved each year if appropriate and affordable vaccines could be made available throughout the developing world.

Through the introduction of innovative financing mechanisms like the Advance Market Commitment, the GAVI Alliance is working to make this vision a reality.

Challenges in developing vaccines for low-income countries

Developing and producing a new vaccine poses huge scientific challenges, can take up to 20 years, and requires a series of large investments. These risks and costs are normally recouped through vaccine sales. However, in the case of vaccines for developing countries, pharmaceutical companies often believe sales will be too small in value to recoup their investment costs. This is because they perceive demand is often unpredictable and poor countries have limited ability to pay.

This situation has meant that there has often been a delay of many years from the time a vaccine is introduced in industrialised countries to the time it becomes widely available in developing countries. Clearly, a new approach to making life-saving vaccines more available – and faster – to developing countries is urgently needed.



GAVI 08 / GAVI OLIVIER ASSELIN

The Solution

An Advance Market Commitment (AMC) is a new approach to public health funding designed to stimulate the development and manufacture of new vaccines for developing countries. In an AMC, donors commit funds to guarantee the price of vaccines once they have been developed. These financial commitments provide vaccine manufacturers with the incentive they need to invest in vaccine research and development, and to expand manufacturing capacity. In exchange, companies sign a legally-binding commitment to provide the vaccines at a price affordable to developing countries in the long term.

An AMC is an innovative solution to give developing countries:

- the RIGHT vaccine
- at the RIGHT price
- in the RIGHT quantity
- at the RIGHT time.

An AMC allows developing country governments to budget and plan for their immunisation programmes knowing that vaccines will be available in sufficient quantity and at a price they can afford over the long term.

The right vaccines

Many safe and effective vaccines already exist, but some of these need to be tailored for developing countries. For example, they may need to be adapted to protect against a particular disease strain that is common in a given region.

In other cases, new vaccines are needed for diseases such as HIV, tuberculosis and malaria. An Advance Market Commitment (AMC) encourages companies to develop and produce vaccines appropriate for developing countries.

The right price

By establishing the price before the vaccine has been developed and production capacity has been built, an AMC helps to ensure that developing countries have access to affordable vaccines – not just in the short term, but for the decades to come.

The right quantity

Even for vaccines that already exist, countries in the developing world currently suffer from regular shortages due to limited manufacturing capacity for these vaccines and limited incentives to scale up production. The AMC addresses this by incentivising companies to enter into long-term and binding supply commitments. AMC resources are made available in line with developing country demand.

The right time

An AMC accelerates the development and manufacture of new vaccines for developing countries. Many companies have vaccines in various stages of development, but under the current system, it will take years for these vaccines to reach developing countries. An AMC spurs companies to develop new vaccines by creating a market for these vaccines once they are ready. It also guarantees affordable pricing for developing countries so vaccines can continue to reach those most in need not just today, but also in the long term.

A sustainable solution

An AMC creates the market conditions that make vaccine development and production for developing countries a worthwhile proposition.

Once reliable markets are assured, and manufacturing capacity developed, market forces can be expected to sustain the system.

A safe investment

An important and unique feature of an AMC is that donor funding is only distributed if a company produces an effective vaccine at an affordable price and if it meets strict criteria set by an independent group of experts. Finally, the vaccines are only purchased if countries demand them. Governments in developing countries will ultimately decide on the product that is right for them.

**“ It’s how you spend
the money
that saves lives”**

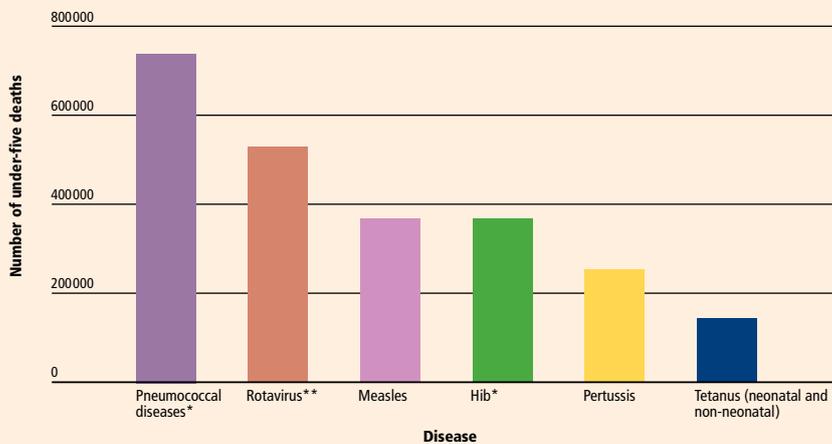
Mary Robinson,
GAVI Alliance Board Chair



The Pneumococcal AMC: from idea to action

The bacteria *Streptococcus pneumoniae*, commonly known as pneumococcal disease, causes a broad range of infections in all populations around the world. Severe pneumococcal disease – primarily pneumonia and meningitis – is the leading vaccine-preventable cause of death in children under five. Nearly one million young children die each year from pneumococcal infection – the vast majority of these deaths occur in developing countries.

**Leading causes of vaccine-preventable deaths
in children under 5 years old**



Source/credits: The Global Burden of Disease: 2004 update.

* WHO/IVB estimates based on GBD estimates, deaths for 2000.

** WHO/IVB estimates based on GBD estimates, 2004 update as of February 2009.

**“The AMC is an important step
towards reducing health inequities
between the rich and poor”**

Julian Lob-Levyt, GAVI Alliance CEO 2005-2010

¹ Donors contributions:
Italy (US\$ 635 million),
UK (US\$ 485 million),
Canada (US\$ 200 million),
The Russian Federation (US\$ 80 million),
Norway (US\$ 50 million),
The Bill and Melinda Gates Foundation
Italy (US\$ 50 million).

The most effective way to prevent these deaths would be to ensure that all children have access to a safe, affordable vaccine.

While a vaccine against pneumococcal disease 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.

In developing countries other serotypes are common, so a vaccine providing broader protection is needed.

The AMC for pneumococcal disease has been developed to make appropriate vaccines available to developing countries sooner and to encourage these countries to set up pneumococcal immunisation programmes.

Global partnership

In June 2009, the governments of Italy, the United Kingdom, Canada, the Russia Federation, Norway and the Bill & Melinda Gates Foundation launched the pilot AMC against pneumococcal disease with a collective US\$1.5 billion commitment (the AMC funds).¹

In addition, GAVI endorsed a budget of up to US\$1.3 billion for the period 2010-2015 to help fund the cost of vaccines. Donor support is crucial for GAVI to purchase the quantity of vaccines necessary to protect the millions of vulnerable children in developing countries and help achieve the Millennium Development Goals.

Thanks to these financial commitments, pharmaceutical companies participating in the Pneumococcal AMC will have an incentive to develop and produce the appropriate vaccines needed in developing countries.

Tangible results

The overarching goal of the Pneumococcal AMC is to reduce morbidity and mortality from pneumococcal disease by introducing effective and affordable vaccines in developing countries.

It is estimated that the Pneumococcal AMC could save approximately 900,000 lives by 2015 and up to 7 million lives by 2030.

The objectives of the mechanism are to:

- **Bring forward the availability** of effective pneumococcal vaccines – through scaling up of production capacity.
- **Accelerate vaccine uptake** – through predictable vaccine pricing for countries and manufacturers.
- **Test the AMC concept** for potential future applications.
- **Accelerate development of new vaccines** that meet developing country needs.

Vaccine price

Under the Pneumococcal AMC firms sign legally-binding agreements to supply their vaccines at a price no higher than US\$ 3.50 for 10 years to be paid by GAVI and the developing country governments that introduce the vaccines.

For approximately 20% of the doses, companies also receive an additional payment of US\$ 3.50 for each dose they provide, which is paid out of the US\$1.5 billion of donor commitments.

This is more than a 90% reduction from the current pricing in industrialised countries.²

As the AMC pilot encourages production from multiple manufacturers, it is expected that competition will drive the price even lower over time.

Which pneumococcal vaccine does the AMC target?

GAVI, through the AMC, funds pneumococcal vaccines that meet the AMC criteria set by a Target Product Profile (TPP), a specification standard developed by the World Health Organization (WHO). In order to be eligible to participate in the AMC, firms must provide vaccines that are tailored for developing countries and cover at least 60% of the prevalent disease strains in the target region and must include serotypes 1,5 and 14 – those that are the most frequent in GAVI eligible countries.

Sustainable solution: country ownership and co-financing

All countries are expected to co-finance the introduction of new vaccines. Co-financing means that countries share the cost of GAVI supported vaccines by procuring some of the required vaccine doses with non-GAVI funds. Co-financing is intended to gradually increase a country's share of the vaccine cost, thus facilitating the sustainability of the country's immunisation programmes and enhancing its own evidence-based decision making. The Pneumococcal AMC will not entail a different co-financing level or mechanism by recipient countries.

The procurement process

The procurement of pneumococcal vaccines is managed by UNICEF. Countries cannot procure pneumococcal vaccines themselves.

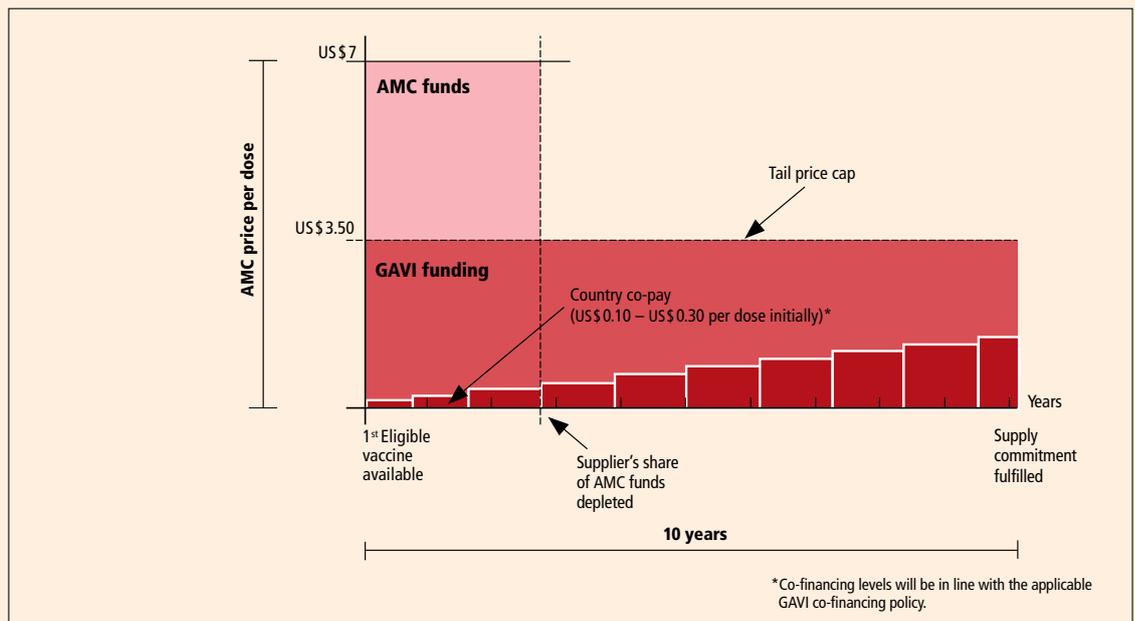
How do countries apply?

The Pneumococcal AMC does not change any of the GAVI standard procedures for countries.

It is a financing mechanism to introduce pneumococcal vaccines sooner and not a separate channel of support for which to apply.

Countries benefit from the Pneumococcal AMC by applying to GAVI for support in the usual way. Several countries have already applied for pneumococcal vaccines and demand is growing dramatically.

AMC funding sources



² Centers for Disease control. CDC website, Vaccine Price List last updated on 8 July 2009. www.cdc.gov/vaccines/programs/vfc/cdc_vac_price_list.htm



The AMC Process

- **Donors** make grant payments to the International Bank for Reconstruction and Development (IBRD). Each donor pays in accordance to its specific schedule or through an agreed demand-based payment arrangement.
 - **IBRD** holds donor payments on its balance sheet. These are designated assets with a corresponding liability and are paid to GAVI under the AMC terms and conditions.
 - **UNICEF** issues calls for offers two times each year based on a 15-year demand forecast that is updated bi-annually by GAVI soon after its Board meetings.
 - **An Independent Assessment Committee (IAC)** of the AMC establishes eligibility of vaccines for AMC funding.
 - **Vaccines** are made available at a maximum price of US\$ 3.50 per dose to be paid by GAVI and the developing country governments that introduce the vaccines. For approximately 20% of the doses, companies will also receive an additional payment of US\$ 3.50 for each dose they provide, which is paid with donor commitments (AMC funds).
 - **Participating manufacturers** must make a 10-year commitment to supply a share of the total demand forecast of 200 million doses annually. The AMC provides a directly proportional share of the US\$ 1.5 billion. For instance, if a firm makes an offer to supply 30 million doses, it is entitled to receive US\$ 225 million, 15% of the total US\$ 1.5 billion AMC funds.
 - **Once a company** has utilised its share of the AMC funds, it is then legally committed to continue supplying its vaccine at the long-term tail price for the remaining period of its supply agreement.
 - **Countries** apply to GAVI for AMC funding according to GAVI procedures. On the recommendation of an Independent Review Committee, the GAVI Board approves the budget for vaccine introduction and annually reviews country progress. Countries contribute to the cost of vaccines based on GAVI's co-financing policy.
- Monitoring and evaluation is conducted under an AMC Monitoring and Evaluation Framework Strategy.
- **All suppliers** that sign a registration agreement of AMC terms and conditions can participate in calls for offers. Offers cannot be higher than the forecasted demand for the start data proposed by the supplier. Offers must have a start date no later than five years into the future.
 - **UNICEF** assesses all offers received and enters into supply agreements with those manufacturers whose products have met the minimum specifications of the target product profile (TPP) developed by WHO.

“It’s a great example of how innovation and technology together can produce life-saving advances and make them available to people who need them around the world”

Bill Gates, Co-chair of the Bill & Melinda Gates Foundation

Frequently Asked Questions

How was pneumococcal disease chosen as the target of the first AMC?

The decision 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 concluded that of the six diseases examined, pneumococcal vaccines were the best choice for the first AMC because of the potential to quickly demonstrate that the AMC concept works and positively impact the health of people in developing countries.

Pneumococcal Disease and HIV

Children infected with HIV are 40 times more likely than other children to become ill from serious pneumococcal infections like pneumonia and meningitis. 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 treatments.

Pneumococcal disease, disability and the poverty cycle

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 disabilities, speech impediments and paralysis. These disabilities affect educational and employment opportunities, contributing to a vicious cycle of poverty and ill health.

Who benefits most from an AMC for vaccines?

Children in developing countries are the big winners from an AMC because they receive the life saving vaccines.

Their families also benefit from children being vaccinated and preventing disease. Otherwise, paying the hospital bills for a sick child may require them to use precious savings or to go into debt. Healthy children have the chance to grow and become valuable contributors to their community's and country's development.

Why not spend the money on medicines 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, never suffers and avoids the potential long term effects of disease. Immunisation through vaccines is often cheaper for the individual and for the health system than treatment. In many places, especially poorer countries, sick people cannot always access medical care to get accurate diagnoses. Additionally, the right treatments might not be available or affordable. Investing in vaccination keeps families healthy and helps to support health systems by reducing the need for treatment of preventable disease.

Pneumococcal vaccines are the right choice for the first AMC because:

- In the case of pneumococcal vaccines it was economics, not science that stood in the way of new vaccines reaching developing countries. For companies that have suitable vaccines in the late stages of development, the AMC provides the motivation to accelerate the process of making them available.
- Success can be easily measured in the adequate supply of new vaccines to meet the developing countries' needs and increased uptake.
- This AMC represents good value for money. Because there is a large global market for pneumococcal vaccines, the AMC leverages 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 only pays for the incremental investment needed to supply developing countries.

More information on the pneumococcal AMC is available at

www.vaccineamc.org



WHO/JONHATAN PERUGIA