

## Why do we need Advance Market Commitments?

**V**accines save lives. Millions of people in developing countries are dying each year from infectious diseases such as pneumonia, tuberculosis, malaria and AIDS. Immunisation is a proven tool to prevent infectious diseases, yet vaccines are not available to children in all countries. The current system is not working. We need to create a new dynamic to accelerate the development, manufacture and introduction of new vaccines for the world's poorest countries.

## What is an Advance Market Commitment?

Advance Market Commitments (AMCs) are a new approach to public health funding designed to stimulate the development and manufacture of vaccines for developing countries. Donors commit money to guarantee the price of vaccines once they have been developed, thus creating the potential for a viable future market. Decisions regarding which diseases to target, criteria for effectiveness, price and long-term availability are made in advance. The donor commitments provide vaccine makers with the incentive they need to invest the considerable sums required to conduct research, train staff and build manufacturing facilities. Developing country governments are thus able to budget and plan for immunisation programmes, knowing that vaccines will be available in sufficient quantity, at a price they can afford, for the long term. By making vaccines available to poor countries more quickly, AMCs will protect children and save lives.

## 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.

*AMCs allow developing countries to choose what vaccines they want.*

AMCs incentivise companies to invest in manufacturing and supplying new vaccines, and in developing future vaccines. But the companies will only be paid if they produce an effective vaccine at an affordable price, and if developing countries want to buy the vaccine. Governments in developing countries will ultimately decide on the product that is right for them.

## Why is an Advance Market Commitment the right solution?

An Advance Market Commitment provides children in developing countries with:

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

It allows developing countries to actually select which vaccines they want, and to choose from a range of suppliers. It is also



a sustainable solution that will ensure the availability and affordability of vaccines well beyond the initial funding period. An AMC is a realistic solution that takes into account the concerns of both consumers and manufacturers, and addresses barriers that exist in the current system. Importantly, an AMC will only pay for success; no money will be paid out until, and unless, a safe, effective vaccine is made available at an affordable price.

### **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.

### **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 stay 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.

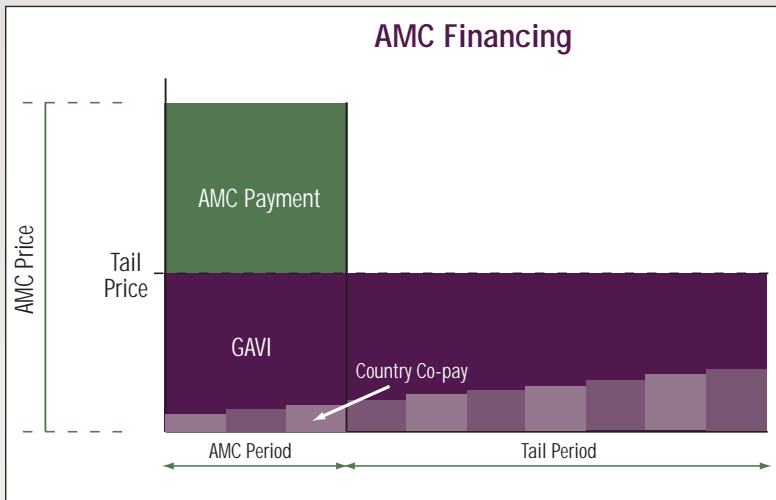
Even where effective drugs exist, treatment is not always as straightforward as it sounds. In many places, especially poorer countries, sick people cannot always reach a hospital or doctor. Even if they do, diagnosis is not always accurate, and the right drugs might not be available or might be too expensive. For some diseases, such as malaria and tuberculosis, drug resistance is making treatment less effective.

### **How do Advance Market Commitments stimulate the development of vaccines for developing countries?**

Given that developing countries have very 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.

### **How will the price of vaccines purchased under an Advance Market Commitment be decided?**

A key objective of an AMC is to ensure that governments in developing countries are able to afford vaccines in the long term. Manufacturers that take part in an AMC will sign legally-binding commitments to supply their vaccine for 10 years at a predetermined low price. In return, companies will receive a higher "AMC price" during the initial years of their commitment.



An AMC acknowledges that vaccine production costs millions of dollars and that it is both reasonable and necessary for companies to recoup these costs. The AMC price companies receive during the initial years of the AMC is designed to provide sufficient incentive for manufacturers to make and recoup the initial investment in developing and/or building manufacturing capacity to supply the vaccines to developing countries.

The AMC price will also include a “co-pay” component to be paid by the government in the developing country that is using the vaccine, and by multilateral agencies such as GAVI and UNICEF, who traditionally assist with vaccine purchase. The country portion of this co-pay will gradually increase over the course of the AMC.

### Who benefits most from an Advance Market Commitment?

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 new 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 Advance Market Commitment, 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 investments.

### When will the Advance Market Commitment start?

Until now, an Advance Market Commitment was just an innovative idea. However, in February of 2007, five governments and the Bill & Melinda Gates Foundation agreed to establish a pilot AMC to accelerate the development and availability of vaccines that

*Children in developing countries are the big winners from an AMC.*

are now expected to save 900,000 lives by the year 2015 and more than 7 million lives by 2030. Italy, the UK, Canada, Russia, Norway and the Bill & Melinda Gates Foundation have pledged US\$1.5 billion for the first AMC, which will become operational by the end of 2008. This pilot will target pneumococcal disease, which causes pneumonia and meningitis and kills 1.6 million people, including 800,000 children, each year.

### Will there be other Advance Market Commitments?

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.



### Who is involved in an Advanced Market Commitment?

An AMC is a cooperative effort. It is based on an acknowledgement that the current system for accessing vaccines does not work in the best interests of those in developing countries and demands a greater effort from each party involved.

- Donor governments and foundations are pledging money. They are undertaking to guarantee reliable funding for new vaccines and they will be paying for part of the cost of the vaccines in the initial period.
- International health and development groups are working together to make AMCs happen. The GAVI Alliance is coordinating these efforts, and The World Bank is managing the finances. The World Health Organization is setting the criteria for vaccine safety and efficacy and UNICEF will be responsible for procurement.
- AMCs will be overseen by an Independent Assessment Committee, which will set and monitor standards for vaccines.
- A large number of stakeholders have been consulted to provide insight regarding how best to establish AMCs.
- The role of the vaccine manufacturer will be to develop the vaccines and build the requisite production facilities to meet the needs of developing countries.