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Advance Market Commitments (AMC)

A new financing model for vaccine introduction

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It can take 10-15 years until an existing vaccine is finally introduced in low income countries, despite their burden of disease and the proven effectiveness of immunization. To accelerate the introduction of new and underused vaccines into poor countries, a new financing model is currently piloted to test its impact on morbidity and mortality of pneumonia. The Advance Market Commitment (AMC) is a new approach to public health funding. However despite its promising outlook, there is a debate about whether the money will be spent wisely.

Immunization is one of the most cost-effective interventions against infectious disease and is estimated that it prevents over two million deaths globally each year. Every year, however, still millions of children die from vaccine-preventable diseases. Most of these deaths happen in the world's poorest countries. Many more lives could be saved if vaccines that are currently in development or in use in high income countries could be made available in low income countries. There are many reasons why people in the developing world are not vaccinated. One important reason is that vaccines against certain diseases have not been developed. In other cases, even though vaccines exist, they do not cover diseases as they present in low income countries, are too expensive or manufacturers do not have the capacity to produce them in the large numbers needed.

The development of a new vaccine poses enormous scientific challenges, requires massive investment and takes many years. Once a vaccine is produced, its sale normally allows a manufacturer to recover development costs. In the case of vaccines produced for low income countries, however, industry has no assurance of recouping its investment. The pharmaceutical industry considers the vaccine market there as both small in terms of purchasing power and risky with unreliable forecasting and purchasing. Poor countries may not be able to afford prices sufficient to cover companies' investment costs and demand for any given vaccine is often unpredictable. There has often been a delay of 10 -15 years from the time a vaccine is

introduced in industrialized countries to the time it becomes widely available in poor countries. (GAVI 2010). It becomes clear that a new approach to making life-saving vaccines more available – and faster – to developing countries is urgently needed.

Innovative strategies by the Global Alliance for Vaccines and Immunisation GAVI

The mission of The Global Alliance for Vaccines and immunization (GAVI) is to save children's lives and protect people's health by increasing access to immunisation in poor countries.

Over the past 10 years, the Alliance has played a crucial role in contributing to the reduction of under-five mortality targeted by the international community in the Millennium Development Goals (MDG) by increasing access to existing and new vaccines. GAVI's achievements are significant. For instance:

- Funding for the delivery of life-saving vaccines to 250 million children
- Averted five million future deaths
- Helped push immunisation rates in some poor counties to an unprecedented 80% average
- Reduced the time lag for the introduction of new vaccines like Haemophilus influenzae type b (Hib) and Hepatitis B, into poorer countries

Importantly, the GAVI Alliance is also developing and implementing new and highly innovative financing aid mechanisms. By stimulating new ways of raising and disbursing money for immunization GAVI tries to make financing for national programs more predictable and sustainable. One such mechanism that draws on private-sector thinking is the Advance Market Commitment (AMC). (GAVI 2010)

Making Markets for Vaccines

In 2005, the Center for Global Development (CGD) published a paper describing an economic and legal framework for funds to incentivize vaccine development. The concept was that making a commitment in advance to buy vaccines if and when they are developed would create incentives for industry to increase investment in research and development. New commercial investment would complement funding of research and development (R&D) by public and charitable bodies, accelerating the development of vital new vaccines for the developing world. This was the initiating idea for the Advance Market Commitment. (AMC). (CGD 2005)

What exactly is an AMC?

An AMC is a new approach to public health funding designed to stimulate the development and manufacture of vaccines for low income countries. An AMC provides a way of accelerating the availability of vaccines for faster introduction in low income countries.

Donors commit money to guarantee the price of vaccines once they are developed, providing that they meet stringent, pre-agreed criteria on effectiveness, cost, and availability, and that developing countries demand them.

These financial commitments provide vaccine manufacturers with the incentive they need to invest in vaccine research and development, and expand manufacturing capacity. In exchange, these companies sign a legally binding commitment to provide the vaccines at a long term affordable price to developing countries. Decisions regarding which diseases to target, criteria for effectiveness, price and long-term availability are made in advance. Developing country governments are thus able to budget and plan for immunization programs, knowing that vaccines will be available in sufficient quantity, at a price they can afford, for the long-term.

An AMC complements existing efforts to increase immunization in low income countries and is a "pull mechanism" to bring extra private sector resources to the aid of public health (GAVI 2010).

Targeting pneumococcal disease

Pneumonia is the single largest cause of death in children worldwide. Each year, pneumococcal disease takes the lives of up to one million children under five years of age, making it the leading vaccine-preventable cause of death among young children. The most effective way to prevent these deaths is to ensure access to effective, safe and affordable vaccines.

Diseases caused by Streptococcus pneumoniae have been identified as a priority area for vaccines. The rapid introduction of these vaccines into the developing world could have a profound effect on childhood mortality.

Although a pneumococcal vaccine has existed since 2000 and is part of regular immunisation programmes in high income countries, countries, there is not a sufficiently effective and affordable vaccine for developing countries. For instance, the currently available vaccine in Europe covers only about 65% of bacterial serotypes prevalent in Africa.

Therefore pneumococcal vaccine covering serotypes in low-income countries was selected to be piloted with for the first AMC. This pilot AMC aims to address this challenge by stimulateing the late stage development, and manufacture and supply of suitable vaccines at affordable prices.

The G7 Finance Ministers endorsed the AMC approach and five donors (Canada, Italy, Norway, UK and Russia, and the Gates Foundation) have committed $1.5 billion to create an incentive for a vaccine against the strains of pneumococcal disease prevalent in low-income countries. In June 2009, after two years of preparatory work, GAVI, the World Bank, WHO and UNICEF, five national governments and the Bill & Melinda Gates Foundation signed legal documents to formally kick-off the fist-ever AMC designed to accelerate access to vaccines against pneumococcal disease.

The currently existing pneumococcal vaccine is sold at over 70 US-$ per dose in industrialised countries. With the AMC, the long term price for developing countries is expected to be US$ 3.50. After 10 years, the end of the AMC funding, the so called tail price will remain at a maximum of US$ 3.50. Implementing countries will provide a small co-payment to contribute towards the cost of the vaccines. The World Bank provides fiduciary support; the World Health Organization has established the minimum technical criteria for a suitable pneumococcal vaccine and UNICEF will be responsible for vaccine procurement and distribution.

Pneumococcal vaccine pricing

GAVI hopes to assist up to 60 of the world's poorest countries to introduce these vaccines by 2015 and it is estimated that this pilot project could prevent more than seven million childhood deaths by 2030.
Lessons learnt from this first AMC will help in the planning of other possible AMCs to tackle diseases such as HIV/AIDS, malaria and tuberculosis (AMC 2010).

Pneumococcal AMC- A promise to children

GAVI announces the vaccine AMC as *"… an innovative way to make vaccines available for children and a promise to children around the world that we will work together to protect them from diseases that currently threaten their lives and cut short their hopes for the future."*

Its goal is to reduce pneumococcal diseases and mortality by introducing effective and affordable vaccines in developing countries.

The debate – will the AMC deliver its promise?

The AMC concept has not only been met with enthusiasm. Besides legitimate questioning and discussion, some serious concerns and criticism has been voiced and published by the Lancet, Health Action International (HAI) and Médecins Sans Frontières (MSF).

The International medical humanitarian organisation MSF warns that while the AMC objective is laudable, the mechanism leaves significant challenges still unmet. Tido von Schoen-Angerer, director of MSF's Campaign for Access to Essential Medicines points out that the overall cost for GAVI of the AMC will be much higher than $1•5 billion because GAVI (through donor funds) will subsidise the tail price. He estimates that the total cost of the AMC will be $3—5 billion (MSF 2009).

Another long-time critic of the AMC concept is Donald Light, visiting professor of Comparative Health Policy at Stanford University, USA. He has written extensively about the AMC, warning that because it is based on a commercial approach to vaccine producers, it results in a price

per vaccine that tops up company profits and remains too expensive for poor country governments.

Light's most recent report was published in 2009 by HAI—a non-governmental organisation working to increase access to essential medicines. In it, he cautions that despite endorsements ranging from the G8 finance ministers, the World Bank to the Vatican, there are reasons for concern about the way the AMC concept is designed.

Because the AMC provides no funding until a new vaccine is fully developed and considered necessary by low income countries, it discourages all but a few large companies to participate because the investment costs remain extremely high. Secondly, its competitive design could undermine cooperative efforts and grant-based "push" funding. Thirdly, by favoring large companies with deep pockets over emerging companies, biotech, university researchers or non-profit institutes that require intermediate funding, AMC could actually decelerate R&D (Light 2009).

Light argues that if the goal were to maximize the number of children saved in the shortest time, one would not consider an AMC approach to a supply contract but work with the pharmaceutical industry to arrange for low-cost production under limited licensing.

He criticizes that…" because AMCs were designed to match corporate revenues and profits in affluent markets, they transform the humanitarian movement from the eradication of diseases of poor people into a for-profit market that is worldwide"….. (Light 2009).

Another publication concludes that "The moral and philosophical measure of success is how much this AMC-like procurement will reduce morbidity and mortality compared with the other ways in which the $1.5 billion could be spent." (Light 2007)

The outome?

A rigorous M&E framework is being developed that will allow GAVI to closely monitor and evaluate the impact of this pilot AMC on pneumococcal disease and mortality. Whether this new financing model will deliver its promise of accelerating pneumococcal vaccine development, supply and coverage in low income countries, saving children's lives will be seen in the years to come. I do certainly hope so.

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References

- GAVI 2010, http://www.gavialliance.org
- CGD 2005, http://www.cgdev.org/section/initiatives/_archive/vaccinedevelopment
- Vaccine AMC 2010, http://www.vaccineamc.org/

- MSF 2009, http://www.msfaccess.org/resources/press-clips/development-today-editorial-on-advance-market-commitment/
- Light D, Advanced Market Commitments- Current Realities and Alternate Approaches, HAI Europe/Medico International, 2009
- Light D, Is G8 putting profits before the world's poorest children? Lancet, Vol 370, July 28, 2007

Other links:

- AMC video by GAVI, http://www.rockhopper.tv/gavi/programmes.aspx?programmeid=247

Advance Market Commitments (AMCs)

Advance Market Commitments (AMCs) are a new approach to public health funding, designed to stimulate the development and manufacture of vaccines specifically for developing countries. The first pilot AMC is for a new vaccine to target pneumococcal disease.

The objectives of the pneumococcal vaccine AMC:

- Accelerate development of vaccines that meet developing country needs.
- 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.

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