

OECD Global Forum on Development

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# Status of the AMCs and future applications

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# The underlying rationale for identifying a new financial instrument to expand Health research

- Vaccination is the most effective way to prevent diseases...
- ... but global resources invested in finding new vaccines are far below the social optimum
- Epidemics control and vaccination are text-book cases of market failure, because of:
  - huge externalities
  - opportunities for free-riding
  - difficulties in protecting intellectual property
  - risk and uncertainties
- The need to establish a market, where one is missing

# Funding the pipeline

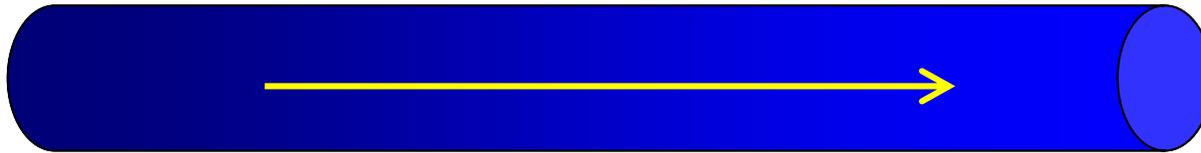
Discovery &  
Research

Clinical  
Development

Licensure

Capacity  
Investment

Supply

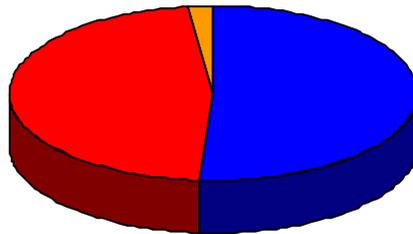


Medicines  
for affluent  
countries



Medicines  
for poor  
countries

Health R&D  
for affluent  
countries  
\$106 billion



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Private  
investment  
to complete  
the pipeline

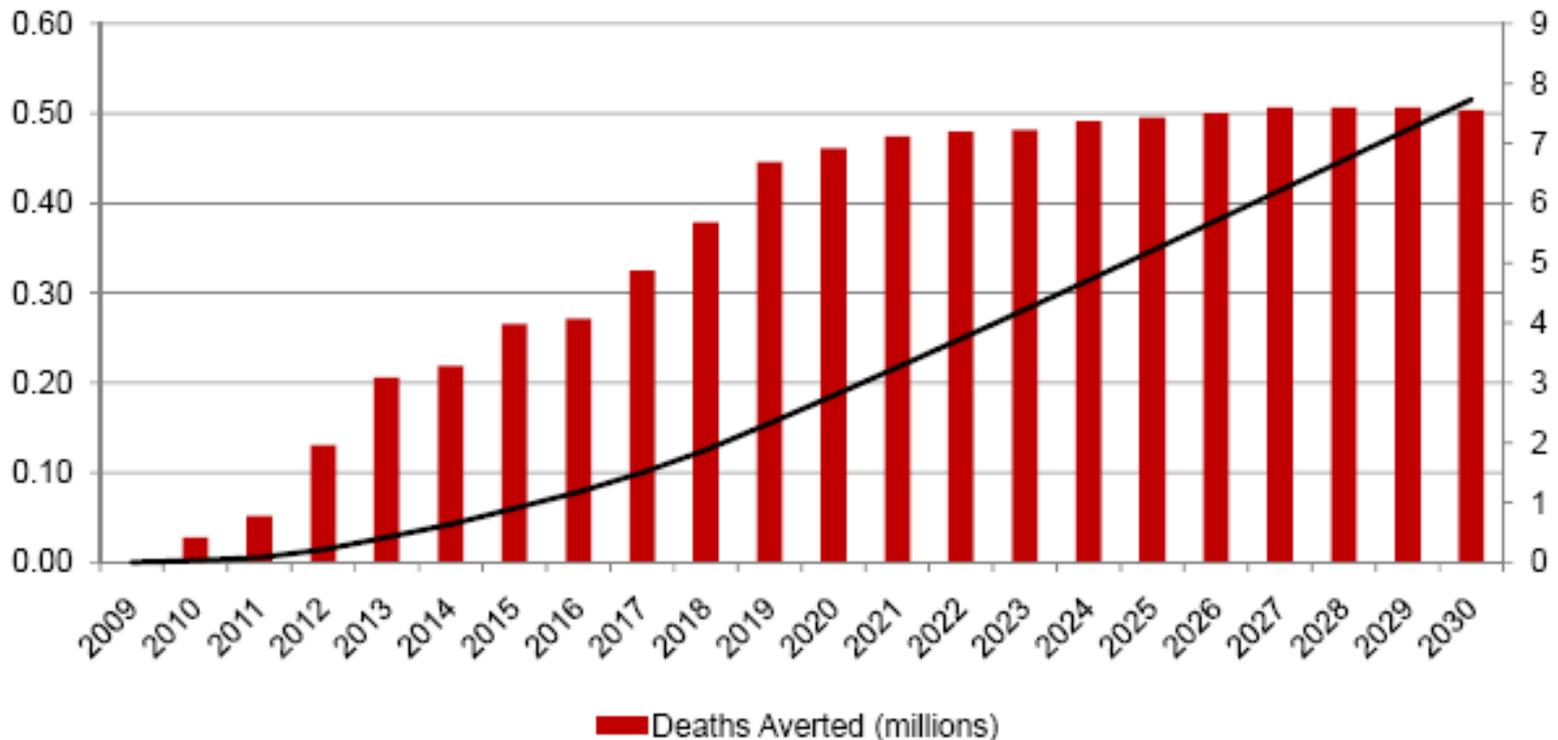
# What is a vaccine AMC?

- An upfront financial commitment by donors, to subsidize the purchase of vaccines at a set price, against a supply commitment from manufacturers, if & when
  - vaccine is discovered/developed
  - meets minimum specified criteria
  - is demanded by poor countries
  - additional production capacity is established

# AMC Objectives

- Overarching aim: preventing the more than 1.6 million deaths from pneumococcal disease every year, of which 800.000 are children
- Accelerate development of pneumo vaccines that meet developing country needs
- Build a competitive market for vaccines (not a purchase guarantee) by ensuring predictable vaccine pricing for countries and manufacturers
- Complement traditional donor financing for vaccine research
- Ensure that when AMC funds are depleted (tail period), manufacturers provide vaccines at a sustainable price

# AMC Pneumo Pilot: Cumulative Deaths Averted



Potential to save approximately 900,000 lives by 2015 and over 7 million lives by 2030.

# AMC:main highlights

- Demand-driven: based on annual country requests
- A “real” PPP: gives a sufficient incentive to private sector to participate, and for the vaccine to be affordable
- Independence: external experts’ panel determines if the vaccine meets WHO specifications
- Value for money: AMCs will lower significantly the cost of net disability-adjusted life years (DALYs) gained (conservative estimates show AMCs are competitive vis-à-vis other alternatives in health)
- Predictability of donor funding: Legally-binding, long-term commitments (as with IFFIm) are taken

# Donor contributions

- Italy - \$ 635 million
- UK - \$ 485 million
- Canada - \$ 200 million
- Russia - \$ 80 million
- Norway - \$ 50 million
- Gates - \$ 50 million

TOTAL: \$ 1.5 billion

# Pilot AMC timeline

- 2000 (approx.): idea of AMC for vaccines put forward in the academia
- February 2005: G7 begins discussions on the APC concept
- December 2005: Tremonti Report on AMCs
- February 2007: Launch of AMC Pilot (1.5 billion pledged)
- Summer 2007-March 2008: Economic Expert Group
- 2007-2008: consultations with pharma and CSOs
- June 2008: GAVI Board endorsement of a 1.3 bn envelope
- July 2008: Final Report of the Implementation Working Group (IWG) on AMC pilot terms
- Early 2009: AMC expected to become operational

# AMC enhanced structure:

- Each company that choose to participate in the AMC makes a binding commitment to supply vaccines for ten years at \$3.50 per dose or less
- In return, the AMC 1.5 bl. subsidy is distributed to the participant companies pro rata on the basis on the fraction of the estimated demand, to the limit of a unit price of \$7
- For risk mitigation, supply agreements include legally-binding commitments by GAVI/donors to buy 20%, 15% and 10% of dedicated supply

# How the pilot AMC works in practice

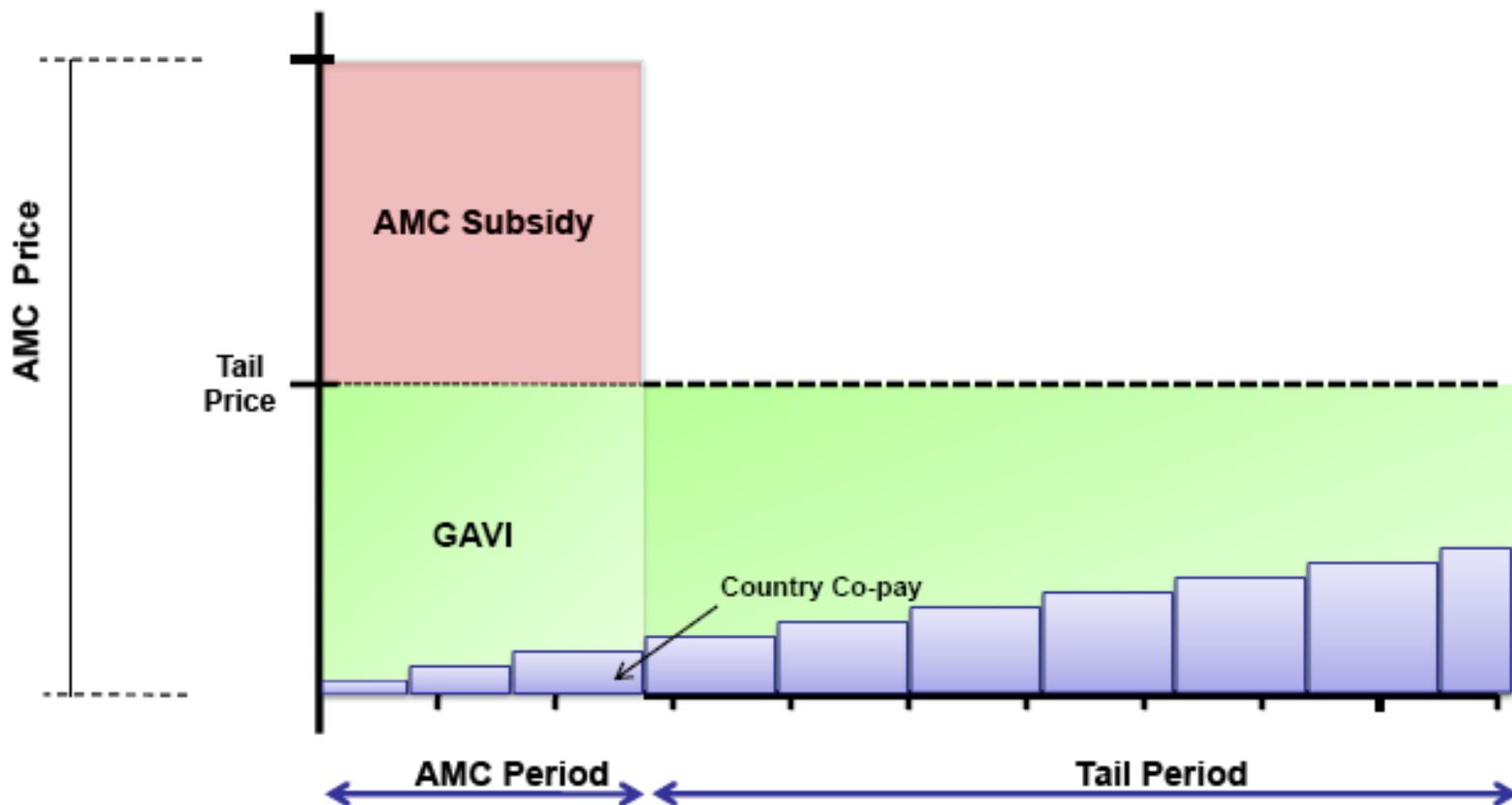
Following the AMC start, all manufacturers who have

- (i) become an AMC-registered manufacturer;
- (ii) produced a vaccine that has been pre-qualified by the World Health Organization;
- (iii) completed the AMC eligibility application process with Independent Assessment Committee (IAC)
- (iv) received approval from the IAC of the vaccine in question as meeting the Target Product Profile (TPP)

are entitled to enter into the AMCs Supply Agreements

(e.g. 10 years of committed supply, with an estimated start date not more than 5 yrs into the future).

# How the pilot AMC works: a snapshot



# Demand-driven nature of AMCs

- Chair of Independent Disease Expert Committee: from a Developing Country
- Country requests determine total supply
- AMC largely similar to existing demand-driven GAVI vaccine support for countries
- Developing countries sit at the GAVI Board
- Countries will choose among the existing alternative vaccines

# Market incentives and competition

- Market entry: Open to all players – multinational and emerging, biotechs and vaccine manufacturers
- Competition: Designed to sustain 2-3 firms to encourage adequate manufacturing capacity and price competition
- Provisional Supply Agreement for emerging countries' manufacturers
- Continued innovation: Designed to last 7-10 years (but not more) to allow multiple products.

# Risks and opportunities

- No easy choice to strike the right balance between the size of the donor contribution against the future benefits
- Trade-off between: the need to provide sufficient incentive to industry to participate (by building dedicated capacity)...
- ....and affordable prices for vaccines in the long run
- Information gap on cost-minimising point in the cost curve
- The proof of concept of the AMC pilot will be whether companies respond to the offer and take on the challenge of supplying the vaccines needed to fight pneumococcal disease. If they do not, no AMC funds will be spent

# AMCs and IFFIm

- By leveraging market resources and/or R&D investments before public money is spent through a long-term legally-binding commitment, AMCs and IFF/IFFIm are similar, yet...
- .. they are quite different in scope and structure:
  - IFFIm aims at frontloading money to buy existing vaccines
  - AMCs are a “pull mechanism” creating markets for products that are not available yet

# Future applications?

- AMCs do have the potential to be applied to other vaccines (malaria)...
- ... as well as to other fields where market failure results in underinvestments in R&D...
- ... also in developed countries, yet...
- ... only the proof of concept from the pilot AMC will respond to these questions...
- .. but only partially, as the nature of each market has to be investigated separately

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Thank you

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