The Pilot Advance Market Commitment
Concept and Development

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Pre-tender meeting
Copenhagen, 10 March 2011
Objectives

- The problem
- The concept
- The Pneumococcal AMC pilot
- How does the pilot work?
- Implications for countries

Photo: GAVI-09-Indrias Getachew
Diseases Affecting Primarily Poor Countries

- Unmet need, high disease burden, no market
- Limited investment by R&D based suppliers
- Solutions are needed to leverage industry expertise and encourage greater investment in innovation for these neglected diseases.
The Concept

- Create a viable market for vaccines in developing countries
- Motivate industry to invest in the needed R&D or manufacturing capacity
- Donors guarantee to support the purchase of targeted products
- Financial commitment should be large enough to cover risk-adjusted costs
AMC Components

- US$
- AMC Price
- Return
- Successful development
- Demand
- Commitment

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The Pneumococcal AMC pilot

Overarching goal: reduce morbidity and mortality from pneumococcal diseases.

- Main objectives:
  - Bring forward the availability of effective pneumococcal vaccines - scale up of production capacity.
  - Accelerate development of second generation vaccines that meet developing country needs.
  - Accelerate vaccine uptake - predictable vaccine pricing for countries and manufacturers.
  - Test AMC concept
Burden of disease

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 at February 2009
Why pneumococcus?

- Major contribution to under 5 mortality
- Economics, not science, is obstacle to introduction in poor countries
- Leverages existing investments
- Focuses on capacity scale-up and reducing manufacturing costs
The Target Product Profile

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Minimal Acceptable Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccines serotypes</td>
<td>• Must cover at least 60% of invasive disease isolates in target region</td>
</tr>
<tr>
<td></td>
<td>• Must include serotypes 1,5,14</td>
</tr>
<tr>
<td>Target population</td>
<td>Prevent disease among children &lt; 5, in particular &lt; 2</td>
</tr>
<tr>
<td>Dosage and schedule</td>
<td>Compatible with national infant immunisation programmes and no more than 3 doses in first year of life</td>
</tr>
<tr>
<td>Routes of administration</td>
<td>Intramuscular or subcutaneous</td>
</tr>
<tr>
<td>Product presentation</td>
<td>Mono-dose or low multi-dose</td>
</tr>
<tr>
<td>Product formulation</td>
<td>Liquid formulation</td>
</tr>
<tr>
<td>Storage and cold chain</td>
<td>Stable at 2-8 °C with minimum shelf life of 24 months</td>
</tr>
<tr>
<td>Product registration and pre-qualification</td>
<td>WHO pre-qualified</td>
</tr>
</tbody>
</table>

Source: Vaccine: pneumococcal vaccine – Technical Product Profile (TPP)  
http://www.vaccineamc.org/updatedec_08.html
How does the Pneumococcal AMC work?

- Italy, UK, Canada, Norway, Russia, Bill & Melinda Gates Foundation have committed to support pneumococcal vaccine market: $1.5 billion (AMC subsidy).

- Interested companies who develop an appropriate vaccine commit to supply certain quantities of the vaccine for 10 years.

- Vaccines are supplied at a price equal or below $3.50 per dose (tail price cap).

- In exchange, as GAVI eligible countries demand the vaccine, companies receive an additional payment to add up to a total of $7 per dose for a maximum of 20% of the doses they provide.

- If the vaccine is not developed or it is not demanded by GAVI eligible countries, the donor funds remain unspent.

- The offer expires in 2020 or as soon as AMC funds are used up.
The process

**Step 1**
Donors provide AMC subsidy

**Step 2**
Manufacturer supply offer

**Step 3**
Application for pre-qualification

**Step 4**
UNICEF procures vaccines from manufacturers

- **Donors**
  - Financial Support

- **World Bank**
  - Financial Management for Donor Funds

- **UNICEF**
  - Procurement Agency

- **Manufacturers**
  - Develop and produce vaccines

- **WHO**
  - Technical support
  - Defines TPPs
  - Pre-qualification

- **GAVI**
  - Financial, Administrative, Programmatic support

- **Countries**
  - Decide to adopt vaccine and co-finance

- **WB**
  - Manages AMC subsidy disbursing it to UNICEF as needed

- **UNICEF Call for Supply Offers**

- **WHO prequalifies pneumococcal vaccine**

- **GAVI Strategic Demand forecast updated biannually**

- **IAC assesses if the vaccine meets the Target Product Profile**

- **GAVI and countries contribute to cost of vaccine**

- **Vaccines are delivered to countries**

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UNICEF Calls for Supply Offers

Guaranteed Demand:
- 25M yr 1 (20%)
- 19M yr 2 (15%)
- 12.7M yr 3 (10%)

Awarded supply

Un-awarded supply available for bidding

Source: AMC website
http://www.vaccineamc.org/files/StrategicDemandForecast.pdf

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Supply Commitments

- Suppliers make 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.

Example:

- Firm A and firm B make an offer to supply 30M doses each (15% of 200M)

- Firm A and B are entitled to US$ 225M (15% each of the total US$ 1.5B AMC)
Funding Sources

<table>
<thead>
<tr>
<th>AMC Price per Dose</th>
<th>AMC funds</th>
<th>$7</th>
</tr>
</thead>
<tbody>
<tr>
<td>$3.50</td>
<td>$3.50</td>
<td></td>
</tr>
<tr>
<td>$2.00</td>
<td>$2.00</td>
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</table>

Funding from GAVI & countries

1st Eligible Vaccine available

Supplier's share of AMC funds depleted

Supply Commitment Fulfilled

10 yrs

Tail price cap

* Co-financing levels will be in line with the applicable GAVI co-financing policy.

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Demand Risk

*Purchase of vaccines from each supplier is dependent on demand*

**Source of risk:**
- Risk is inherent in binding supply commitment
- Fear of demand over-estimation
- Funding contingent upon long-term ODA commitments and country co-financing

**Mitigation:**
- AMC subsidy provides financing for capital cost
- Fast AMC subsidy payout for early cash flow
- Partial demand guarantee to ensure subsidy payments (45% of one year peak demand – firm order timing)
- Opt-out provision if demand absent
- Production planning based on the rolling 12-months demand forecast by UNICEF
Economic Adjustments for Inflation

At request of manufacturers,

- IAC will increase the tail price annually up to the cap (US$ 3.50) at the rate of inflation (OECD)

- IAC will consider an increase in the tail price cap (over US$ 3.50) at rate of inflation (OECD):
  - Each third anniversary of 12 June 2009 or
  - Every time 7% cumulative inflation since 12 June 2009 or latest inflation review (OECD)

Requests for increases above inflation rate must be accompanied by relevant Cost Information
What it means for countries

- GAVI Eligible Countries: countries can apply for GAVI support for the introduction of Pneumococcal vaccines through the regular process.

- Countries express their preference on pneumo vaccines
- GAVI co-financing and default policies will apply to the AMC without modifications
- Vaccines are procured through UNICEF
Grandfathering of the AMC

- Following the new eligibility policy, in June 2010 the GAVI Board approved the grandfathering of the AMC:
  - All 72 GAVI eligible countries (2003 definition) have access to PCV through GAVI at the AMC terms and conditions.
  - Graduated countries will need to completely self-finance the vaccine price (tail price) once GAVI support has ended.
  - All countries must have achieved the DTP3 coverage above 70% in order to purchase under the AMC agreements.

- May 2011 application round:
  - Last opportunity for graduating countries to receive GAVI support for the introduction of PCV – co-financing level will increase by 20% each year to reach 100% by 2016.
  - Application of the DTP3 coverage filter (70%) suspended

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Market impact

Scale up of production capacity: 200M doses per year

Development of new pneumococcal vaccines

Multiple suppliers: More choice for countries and price decline
More than 7 million deaths averted by 2030
Thank you