An Advance Market Commitment for new vaccines
The Pneumococcal Pilot

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Objectives of the presentation

- AMC Concept & the pneumo pilot
- Terms of the deal in detail
- Progress to date

Source: UNICEF
What is an AMC?

- An AMC creates *market conditions to stimulate private investment* in vaccine R&D and manufacturing capacity for future vaccines.

- An AMC requires donors to make *legally binding financial commitments* to support a market of a pre-agreed value.

- **Companies** participating in an AMC agreement *commit to supply* a successful vaccine at a long term price below a pre-set cap (tail price cap).
What is an AMC? (cont.)

• An independent assessment committee (IAC) determines whether the vaccine meets pre-specified criteria (TPP).

• Then, as long as there is effective demand from developing countries, the company can receive the funds from the AMC as a top up to the long term price (AMC funded price).

• Once the AMC is exhausted, companies are required to ensure the supply of the vaccine at the lower long term price.
Pneumo pilot


- Financial commitment: $1.5 billion from Italy, UK, Canada, Norway, Russia, Bill & Melinda Gates Foundation

- Tail price cap: $3.50

- Vaccine purchase price: $7 (i.e. tail price + AMC funded price)

- Demand forecast: reaches 200M doses in 2020

- Stakeholders: AMC Donor Committee, GAVI, GAVI-eligible countries, suppliers, UNICEF, World Bank, WHO.
Terms in detail: 1 - AMC Price

Vaccine Purchase Price: $7 (i.e. tail price + AMC funded price)

Tail Price Cap: $3.50

AMC Envelope: $7.00

Top up: + $5

Top up: + $3.50

GAVI: $2.00

Tail Price Cap: $3.50
2 - Supply Commitments

10-year supply commitments by industry to build adequate capacity for GAVI countries

AMC Envelope of $1.5 B
200 M annual doses

Firm A commits to supply 50M doses per year or 25% of the total (200M) doses = $375M of the total $1.5B AMC

- Primary benefit: aligns AMC resources directly with desired AMC outcome
- Each supplier will have its pro rata share – improvement of sequential tendering
Example:

- Firm A commits to supply 50M = $375M of the total $1.5B AMC
- $375 M disbursed at a rate of $5.00 per dose (top up)
- $375 M/$5.00 = 75M doses at $7
- 75M/50M = 1.5 years AMC period
- 8.5 years of supply at $2.00 = tail period
3 - Matching capacity to demand

- The entire $1.5 billion aggregate AMC contribution is on offer at the launch of the pneumo-AMC

- Bids must have an estimated start date no more than 5 years into the future (meanwhile suppliers can sell existing manufacturing headroom)

- The bid cannot be higher than the forecasted demand for the start date

- Once projected demand for a given year is met, commitments would no longer be accepted for that year
Example:

- Firm A makes a bid in 2009 for the 100M doses = $750M of the total $1.5B AMC
- In 2013 Firm A makes a bid for an additional 60 M doses = +$ 450 M
- In 2015 Firm B makes a bid for an additional 40 M doses = $300 M
4 - Mitigate risk for companies

Two incentives will help ensure dedicated capacity

1. Frontloading by making initial “AMC price” sufficiently high

2. Provide limited demand assurance (firm order timing):
   At the time of signature of the supply agreement, the AMC donors & GAVI will make a legally binding commitment to buy 20, 15 and 10 % of the supplier’s dedicated capacity in years 1, 2 & 3, respectively
5- Integrate AMC with GAVI procedures

- Pneumococcal vaccine introduction and delivery systems aligned with other GAVI support

- Example: using existing co-financing mechanism provides predictability for countries
  - Recognition of differing ability to pay
  - Follow GAVI default policy
Example: GAVI co-financing policy

** Will be requested to increase payment 15% annually
Progress to date

- **2007**
  - Launch in Rome in February
  - Role of different organisations defined

- **2008**
  - IAC members selected

- **2009**
  - TPP approved by DG of WHO
  - Terms of the deal defined – IWG report published July 2008
  - M&E Study and Framework
  - Signature of Legal agreements
Thank you!

Source: GAVI
# Target Product Profile

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<th>Minimally Acceptable Profile</th>
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| Vaccines serotypes                | * Must cover at least 60% of invasive disease isolates in target region  
|                                   | * Must include 1,5,14         |
| Immunogenicity                    | In accordance with WHO criteria: non inferiority to a licensed pneumo vaccine |
| Target population                 | Prevent disease among children < 5, in particular < 2                       |
| Safety, reactogenicity            | Similar to currently licensed vaccine                                    |
| Dosage and schedule               | Compatible with national infant immunisation programmes and no more than 3 doses in first year of life |
| Interference                      | No significant interaction or interference with currently administered vaccines |
| Routes of administration          | Intramuscular or subcutaneous                                             |
| Product presentation              | Mono-dose or low multi-dose                                               |
| Product formulation               | Liquid formulation                                                        |
| Storage and cold chain            | Stable at 2-8 °C with shelf life of at least 24 months                    |
| Packaging and labelling           | In accordance with WHO recommendations                                    |
| Product registration and pre-qualification | WHO pre-qualified                                         |
| Post marketing surveillance       | In accordance with national regulatory authorities and WHO prequalification requirements |
Legal structure

AMC Agreements
1. Donor Grant Agreements
2. Stakeholder Agreement
3. Offer Agreement with Terms & Conditions
4. Pro-forma Supply Agreement

AMC-Eligible Vaccine

IAC Charter and Bylaw

Licensed by stringent regulatory authority/WHO PQ Vaccine

Supply Agreement UNICEF/Supplier

SUPPLIERS