Procurement of Pneumococcal Vaccines under the Advance Market Commitment

Pre Tender Meeting
UNICEF Supply Division, 10-11th December 2008
Ann Ottosen
From 2009 and 2010, 11 GAVI-supported countries are approved to introduce PCV, 8 countries with supply through UNICEF

- 2 countries to introduce PCV7 in 2009 of PCV7 through a donation, 6 to introduce vaccines with more serotypes by 2010, covering a birth cohort of ~6.2M children
- Demand based on current GAVI approvals 2009: ~8M doses, 2010: ~20M doses, 2011: ~21M doses
- 11 countries are currently considering introduction and could apply in future for introduction after 2009, covering a birth cohort of 7M children
Overview of the AMC from a Supplier’s Perspective
How to become an AMC Registered Manufacturer (1/2)

Manufacturer to submit an AMC Registered Manufacturer Application Package to the AMC Secretariat

- Applicant’s legal status and registration/corporate incorporation information
- Manufacturing license and/or company registration with NRA
- Information on vaccine production, supply and delivery activity, if any, including an overview of any existing vaccine portfolio, number of years of production and supply of such vaccines, quantities supplied annually for the past three years and the number of countries in which such vaccines have obtained a product licensure and in which they are currently marketed
- Estimated timeline for applying to the Independent Assessment Committee (IAC) to have a Vaccine considered Eligible for AMC supply
How to become an AMC Registered Manufacturer (2/2)

Manufacturer to enter into an AMC Registered Manufacturer Agreement between Manufacturer, GAVI Alliance and the International Bank of Reconstruction and Development (IBRD)

- Acknowledges and agrees to the terms and conditions of the Offer Agreement (incl. AMC T&C and Pro-forma Supply Agreement)
- Acknowledges that determinations of AMC Eligibility is at the sole discretion of the IAC
- Commits to provide an **annual update of timelines** to apply for Vaccine Eligibility
- Unconditional and express waiver of all claims against any entity involved in the AMC are not responsible for any liabilities, claims, actions, damages, losses……arising from the applicants participation in the AMC…
UNICEF Call for Supply Offers under the AMC (1/2)

UNICEF to issue first Call for Supply Offers upon

a) Donors’ Offer made public, including an updated GAVI Strategic Demand Forecast – expected Spring 2009

b) AMC Registered Manufacturers

Example of a GAVI Strategic Demand Forecast as shared with industry during AMC consultations (Dec 2007, not based on current approvals)

Last call for offers in 2020 or when the total AMC funds of US$1.5B have been fully committed, which ever comes first
UNICEF all for Supply Offers under the AMC (2/2)

UNICEF to issue subsequent Calls for Supply Offers

- Update of the GAVI Strategic Demand Forecast following review of new country applications – twice annually
- There is a minimum unmet demand of 10M doses within the upcoming 5 year period

Example of annual quantities to be requested based on the GAVI Strategic Demand Forecast
Proposals from Manufacturers under the AMC (1/3)

Technical and Mandatory Financial Requirements

• Financial information to allow evaluation
• Registration on United Nations Global Marketplace
• Documentation, if applicable, that the PSF is accepted for review by WHO (requirement for Provisional Supply Agreements)
• Supplier’s Vaccine Production Plan

Quantitative Requirements

• Commencement date of the Vaccine Purchase Period offered
• Annual Supply Commitment Quantities for 10 years
• Price quotation for the Tail Price in USD
• Production and Availability Forecasts
Qualitative Requirement

- Description of vaccine, including schedule, standard shelf life, vial size, presentation(s), weight and volume
- Number of years of production and delivery of the offered vaccine
- Correlation with production of other product
- Experience in vaccine production and delivery of similar scale
- Quality aspects, including quality control and past non-compliance or irregularities
- Account management information
1. Product and Production Capacity Development
   - Product status and plans (e.g. planned presentations and packaging, capacity, source of bulk antigens)
   - Description of production site(s) and timelines for development
   - Clinical trials conducted and planned with timelines
   - Post-marketing surveillance strategy
   - Status and timelines for facility approvals

2. Status and plans for regulatory licensure, NRA and WHO prequalification and IAC application for eligibility of vaccine, if applicable

3. Expected date for providing a Vaccine Purchase Period Trigger Notice

4. Expected date for commencement of the Vaccine Purchase Period

Technical Review of Proposal by WHO
Assessment of Supply Offer under the AMC

A Supply Offer will be assessed based on

- The ability to support the AMC Objectives regarding Supply Commitment Quantity offered and timelines for availability
- The feasibility of the Supplier’s Vaccine Production Plan for the production of the Supply Commitment Quantity
- The offered Tail Price
- Supplier’s experience in vaccine production and delivery of similar scale and past performance record with UNICEF, if applicable

Additional demand and market specific elements

- Ensuring supply for the actual demand as represented by the GAVI approved quantities for each GAVI Eligible Country and forecasts;
- GAVI Eligible Country preferences for a particular product as indicated in the respective Eligible Country Applications; and
- The objectives of assuring an uninterrupted, sustainable supply of vaccines of assured quality and contributing to the creation of a healthy vaccine market including multiple manufacturers

UNICEF to receive advice from a Procurement Reference Group
How to become Eligible to enter into a Supply Agreement under the AMC

Supplier to submit an application for AMC Eligibility to AMC Secretariat

- Documentation that the PSF has been accepted by WHO for review
- A copy of the PSF forwarded to WHO
- Target Product Profile Eligibility Justification Document (describing how the product meets the TPP)
  - IAC to review application and raise potential questions for WHO to consider during prequalification

Assessment of application for AMC Eligibility

- Upon prequalification, IAC will review if the vaccine meets the TPP (within 30 days from PQ)
- Communicate to applicant if a proposed vaccine is considered eligible or not (within 15 days after IAC review)

Annual deadlines 30 days after WHO application deadlines (Feb, June, October)
Entry into (Provisional) Supply Agreements

✓ GAVI confirmation that any Agreement is consistent with the AMC legal framework
✓ GAVI Board approval of the applicable budget for each Agreement

Entry into a Supply Agreement between UNICEF and Supplier

• Supplier meets all requirements including AMC Eligible vaccine
• Offer has been assessed and found acceptable
• Quantities have been negotiated, if needed, to meet objectives

Entry into a Provisional Supply Agreement (PSA), provided

• The aggregate doses of AMC-Eligible Vaccine under all existing Supply Agreements and Supply Agreements that are being negotiated are insufficient to meet projected demand for the immediately following 5 years
• The PSF has been accepted for review by WHO, but not approved
• The Supply Offer meets the requirements and will contribute to the AMC objectives

➢ A PSA is automatically changed into a Supply Agreement upon a positive IAC determination of eligibility in accordance to timelines specified by the manufacturer in the Supplier’s Vaccine Production Plan
Mutual commitments under a Supply Agreement (1/2)

Supplier’s commitments

• An Annual Supply Commitment Quantity to be made available for 10 years
• A date for commencement of Vaccine Purchase Period (availability of Annual Supply Commitment Quantities, max. 5 years from signing of Agreement)
• A date for formal notification that the VPP will start in accordance to contract (3 months before VPP)
• A Tail price at a maximum of US$3.50
• Twice annual updates on the Supplier’s Vaccine Production Plan until commencement of VPP

Supplier’s opportunities

• Provisions for supply prior to the VPP (provided that there is demand)
• The option to reduce the 10 year duration through supply prior to the VPP
• The option to increase total quantities on Supply Agreement
Partners’ commitments

- A frontloaded price of US$7 per dose
- A firm purchasing contract for 20%, 15%, 10% of the annual Supply Commitment Quantity for the first 3 years of VPP
- Provisions for how to reduce the Annual Supply Commitment Quantities in case of delay in demand or demand below actual committed quantities through UNICEF Annual Demand Forecast
Serious pneumococcal diseases are the primary vaccine-preventable cause of death in children under 5. The AMC could potentially save 900,000 lives up to 2015 & 7.7 M lives up to 2030.
The Pneumo Advance Market Commitment – a pilot (2/2)

Currently an opportunity for industry to obtain final drafts of core AMC agreements and provide key concerns in writing against signing a confidentiality agreement with World Bank.

- Offer Agreement incl. AMC T&C and Supply Agreement
- AMC Procedures Memorandum
- AMC Registered Manufacturer Agreement
- IAC Charter and Bylaws
- Master Definition Agreement

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Deadline for receipt of comments 29 December
Thank you
AMC Objectives

1. To accelerate the **development** of pneumococcal vaccines that meet developing country needs (e.g. serotype composition and vaccine presentation) as specified in the Target Product Profile (TPP).

2. **To bring forward the availability** of effective pneumococcal vaccines for developing countries by guaranteeing the initial purchase price, for a limited quantity of the new vaccines, that represents value for money and incentivizes manufacturers to invest in scaling-up production capacity to meet developing country vaccine demand.

3. **To accelerate vaccine uptake** by ensuring predictable vaccine pricing for countries and manufacturers, including binding commitments by participating companies to supply the vaccines at low, long-term and sustainable prices after the AMC finances are depleted.

4. **To pilot test the effectiveness** of the AMC mechanism as an incentive for needed vaccines and to learn lessons for possible future AMCs.