Procurement of Pneumococcal Vaccine under the Advance Market Commitment Terms and Conditions

AMC Pre-tender meeting
Copenhagen, 10 March 2011
UNICEF SD
Presentation Overview

1. Update on Pneumo Vaccine demand and supply as of today
2. Second Call for Offers under AMC
1. Update on Pneumococcal Vaccine demand and supply as of today
GAVI approvals of introductions of Pneumococcal Vaccine

- 2 countries have introduced PCV7 in 2009, to switch in 2011
- 17 additional countries approved to introduce in 2010-2012
- 5 countries conditional approval

Birth cohort of 17M

Birth cohort of 5M

- 20 new countries expected to apply for support in next application round in May 2011
Four suppliers made a proposal in response to the first AMC tender in 2009.

The eligible suppliers awarded long term Provisional Supply Agreements for a total of 30M doses annually for 10 years to start in 2012 and 2013.
Country introductions:
5 already introduced, 3 scheduled in Q1-2 2011

<table>
<thead>
<tr>
<th>Countries</th>
<th>Introduction date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicaragua</td>
<td>December 2010</td>
</tr>
<tr>
<td>Guyana</td>
<td>January 2011</td>
</tr>
<tr>
<td>Kenya</td>
<td>January 2011</td>
</tr>
<tr>
<td>Sierra Leone</td>
<td>January 2011</td>
</tr>
<tr>
<td>Yemen</td>
<td>January 2011</td>
</tr>
<tr>
<td>Mali</td>
<td>March 2011</td>
</tr>
<tr>
<td>Congo, DR</td>
<td>March 2011 (phased intro)</td>
</tr>
<tr>
<td>Honduras</td>
<td>April 2011</td>
</tr>
</tbody>
</table>

• Anticipated upcoming country introductions:
  • 6 midyear
  • 5 Q4 2011/Q1 2012
Country introductions:
5 already introduced, 3 scheduled in Q1-2 2011

<table>
<thead>
<tr>
<th>Countries</th>
<th>Introduction date</th>
<th>Intro date in application</th>
<th>Approval date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sierra Leone</td>
<td>January 2011</td>
<td>January 2010</td>
<td>July 2008</td>
</tr>
<tr>
<td>Yemen</td>
<td>January 2011</td>
<td>March 2009</td>
<td>November 2008</td>
</tr>
<tr>
<td>Mali</td>
<td>March 2011</td>
<td>January 2010</td>
<td>July 2009</td>
</tr>
<tr>
<td>Congo, DR</td>
<td>March 2011 (phased intro)</td>
<td>January 2010</td>
<td>July 2008</td>
</tr>
<tr>
<td>Honduras</td>
<td>April 2011</td>
<td>January 2008</td>
<td>November 2007</td>
</tr>
</tbody>
</table>

• Products first approved by AMC IAC for supply May and September 2010
• First vaccine deliveries September and November 2010
• First introductions currently going on – country readiness in cold chain cause of delay
AMC funds available for future agreements

+$1B remains available for future supply agreements to:

- incentivize manufacturers to accelerate development and availability
- contribute to creation of healthy market with multiple suppliers
- enhance the possibility to access lower long term prices

Tail Prices likely to drive future country product preferences:

- New GAVI co-financing policy requires 16 countries to ramp up co-financing over 4 years to reach 100% in 2016
- 2 about to introduce, 6 are expected to apply for introduction in 2012 or 2013
To sum up....

Country introductions of Pneumo Vaccines at an unprecedented rate compared to Penta (19 first countries in 12-15 months)

Expected continued high interest from new countries

Supply under current contracts almost match overall demand

+$1B/70% of AMC funds remain available for future awards
2. Second Call for Offers for PV under AMC terms and conditions
## Timeline for Request for Proposal

<table>
<thead>
<tr>
<th>No</th>
<th>Activity</th>
<th>Period</th>
<th>March</th>
<th>April</th>
<th>May</th>
<th>June</th>
<th>July</th>
<th>Aug</th>
<th>Sept</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pre-tender meeting</td>
<td>10-Mar</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Issuance of Call for Offers*</td>
<td>08-Apr</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Clarifications as needed</td>
<td>09-Apr to 05-May</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Receipt of Proposals</td>
<td>06-May</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Review of Proposals (WHO/UNICEF)</td>
<td>09-May to 01-Jul</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Clarification meetings with industry</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Evaluation of Proposals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Procurement Ref Group consultation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>UNICEF recommendation and approvals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Award letters to be issued</td>
<td>01-Jul</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>UNICEF/supplier agree in principle to SA</td>
<td>04-Jul to 29-Jul</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Entry into SA with supplier</td>
<td>01-Aug to 09-Sept</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- GAVI SA consistency review</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- GAVI Board approval of SA incl. firm contract commitment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Assuming publication of the GAVI Strategic Demand Forecast 11 March

- Due to cycle of GAVI approval process this year, visibility of near term demand only available in Aug/Sept (will not be available with awards in July)
SDFs and Call for Offers

GAVI shall publish the SDF annually as soon as the necessary information is available from the last procurement cycle and relevant GAVI Board meeting.

- The SDF outlines the estimated demand, the estimated supply and the estimated shortfall for which Call for Offers are made.

A Call for Offers may be issued once per calendar year or more or less frequently if so decided by the AMC Secretariat in consultation with UNICEF.

- A written explanation of the decision to issue or not will be provided to the AMC Stakeholders.
SDFs and Call for Offers

Triggers of a Call for Offers

- AMC Registered Manufacturers (registration confidential, but four known)
- Consultation with AMC Secretariat
  - Publication of GAVI Strategic Demand Forecast (assuming 11 March)

Entry into Supply Agreements provided

- Increase in GAVI SDF by \( \geq 10M \) doses annually for next 5 years, or
- Unallocated quantities which exceed 10M doses annually
- GAVI Board has approved firm contracting commitment
- Procurement agency internal procedures and processes complied with
Procurement Objectives

1. Bring forward the availability of effective pneumococcal vaccines - ensuring supply for the actual demand as approved

2. Selecting products and presentations that best meet the country needs (including prices)

3. Continued vaccine supply and contributing to the creation of a healthy vaccine market including multiple suppliers

PURPOSE:
To ensure access to a sustainable supply of PV from AMC Registered Manufacturers to meet demand from 2016-2025
• Maximum quantity that could be awarded for 2016 is 74M dose
• Actual quantity to be awarded to be based on assessment on how best to meet procurement objectives considering advice from a Procurement Reference Group
Uncertainties related to forecasting accuracy

Early forecasts tend to be more optimistic in terms of starting date of uptake

The SDF model being refined to predict long term demand as new evidence on country demand is established

Lessons learned from HepB and Hib forecasting – vaccine volumes highly dependant on actual year of intro from a small number of very large countries

- Demand from 6 large countries (IND, PAK, DRC, NIGR, BANG, ETH) make up 51% by 2016 (3 already approved: DRC, Ethiopia, Pakistan)
Uncertainties related to forecasting accuracy

Actual demand determined by changes in GAVI policies (e.g. coverage filter and eligibility – catch up? Application guidelines?)

Actual demand from new countries dependent on one product per round and GAVI funding availability (Prioritisation)

Impact of new eligibility and co-financing levels on country willingness to apply remains to be seen

Readiness of countries to introduce varies greatly from 1-15 months from supply availability (cold chain, training)
UNICEF procurement forecast

- Predictable demand +10-20M doses compared to contracts
- Likely demand appx. additional +20M doses (assume 2012 intro)
- Possible demand includes applications from new countries expected based on projections of SDF
Mandatory Requirements

Technical and Financial Mandatory Requirements to be reviewed by UNICEF and WHO

- For vaccines not yet approved by IAC, written confirmation from WHO of acceptance of PSF, if applicable
- Most recent Audited Financial Statement
- Quality System Certificate
- UNGM code
- The Supplier’s Vaccine Production Plan, etc.

Only Proposals submitted by AMC Registered Manufacturers can be reviewed

...and that Manufacturers should submit offer if a product in pipeline to ensure best basis for award decisions
The Supplier’s Vaccine Production Plan (1/2)

Product and production capacity development to be reviewed by WHO

• Status and plans, sourcing of bulk, planned presentations and packaging, capacity
• Description of sites and timelines for development
• Clinical trials conducted and planned, timelines
• Post marketing surveillance strategy
The Supplier’s Vaccine Production Plan (2/2)

Licensure timelines and supply availability to be reviewed by WHO and UNICEF
• NRA status and plans for registration, and release NRA
• WHO pre-qualification timelines, if applicable
• Timeline for forwarding application for Eligibility
• Status and timelines for submission to NRA and WHO for approval of manufacturing site
• Expected date for providing Vaccine Purchase Period Trigger Notice (at the latest 3 months before Vaccine Purchase Period)
• Expected date for commencement of the Vaccine Purchase Period

All Registered Manufacturers expecting to have a vaccine available no later than 2016 should submit a proposal
Qualitative Requirements are standard

Qualitative Requirements

• Product including serotypes, vaccination schedule, shelf life, presentation including vial size, weight and volume
• Number of years the manufacturer has produced and delivered the offered product(s), if applicable
• Impact on production of other products, if applicable
• Experience in vaccine production and delivery of similar scale to that offered
• Quality aspects, including quality control and any past non-compliance or irregularities
• Account management information
AMC specific quantitative requirements

Quantitative Requirements

- Supply Commitment Quantities on an annual basis for the Vaccine Purchase Period
- Commencement date of 10 year Vaccine Purchase Period
- Price quotation for the Tail Price in US$ (initial price fixed at $7.00 by AMC model)
- Production and availability forecasts

Manufacturers may make several proposals with different commencement dates and for alternative presentations
Assessment of Proposals

Assessment of Supply Offer and determining award quantities to a supplier

- Ability to meet Objectives including quantities offered and timelines for availability
- Feasibility of the Supplier’s Vaccine Production Plan
- The offered Tail Price including any waiver or modifications of the inflation adjustment provisions
- Experience in vaccine production and delivery of similar scale
- Past performance record with UNICEF, if applicable
Award recommendations

UNICEF

• Will base award recommendations on assessment of the offer and the WHO technical review, to be presented to PRG for advise and to be approved in accordance with UNICEF’s standard processes

• May enter into a Supply Agreement with an AMC Eligible Manufacturer and a Provisional Supply Agreement for vaccines which have been accepted for review by WHO

• May decide to award less than the total quantity forecasted if it is considered that vaccines in pipeline could reach the market within the next 5 years to better meet any of the objectives, including multiple suppliers and lower Tail Prices
Confidentiality around Proposals/Call for Offers

Confidentiality

• All information provided by a supplier as part of the Proposal is considered confidential. Members of the Procurement Reference Group and the WHO technical reviewer sign confidentiality agreements with UNICEF.

• Due to the strategic nature of vaccine development projects, there will be no public opening.
Publication of outcome of Procurement Process

UNICEF will publish

• Awards for Supply Agreements on the UNICEF website indicating name of manufacturer, value and duration of Supply Agreements, and Tail Price

• Names of manufacturers submitting a proposal but not awarded, unless specifically requested to keep name confidential

GAVI will publish

• No later than 5 days following the execution of an Agreement a notification on the AMC website disclosing date of entry into and the parties of a Supply Agreement/Provisional Supply Agreement (publicly available Annual Supply Commitment Quantity, Tail Price, start date of Vaccine Purchase Period, and total headroom supplies)
In conclusion....
In conclusion…

Second Request for Proposal/Call for Offers under AMC planned to be issued 8 April

Any manufacturer expecting to be able to have supply available to UNICEF prior to or no later than 2016 should register and submit a Proposal

Award letter(s) to be issued 1 July

AMC Provisional Supply Agreements and/or Supply Agreements following this Call for Offers to be entered into at the latest early September

Early supply requirements based on country demand for first deliveries after receipt of applications, recommendations and financial approvals in August/September
Thank You