UNICEF supply update for OPV

Seventh WHO/UNICEF Consultation with OPV/IPV Manufacturers and NRAs

UNICEF Supply Division
30 October 2008
Geneva
Vaccine Security and provision of OPV

Vaccine Security – that is sustained and uninterrupted supply of affordable polio vaccine of assured quality – has been and will continue to be a key objective for UNICEF.

The conditions and premise for ensuring Vaccine Security are complex as the programme recommendation moves with refined tools from massive campaign requirements, to targeted products – and eventually cessation after Certification.

UNICEF and WHO believes that the key to ensure polio vaccine security is a continued dialog with the vaccine manufacturers on current short term demand and supply planning, as well as current information sharing on strategic decision concerning the Programme and the general vaccine production.

• 2009 include awards, plus potential India and Pakistan additions
• 2010 The split between mOPVs continue to need refinement as we move forward
Status of 2008 utilization of LTAs

2008:
tOPV – expect utilization rates of around 70% of LTA quantities, as has been consistently communicated to manufacturers. The reason being the increased use of mOPVs.

mOPV1- 100% utilization of 2008 LTAs. Substantial additional awards have been made throughout the year.

mOPV3 – 100% utilization of LTAs for 2008. Timing of utilization for India is likely to extend into early Q2 2009 as anticipated in the original tender. The delayed uptake is due to a shift towards mOPV1 demand.
Establishment of 2009-2010 LTAs

In July 2008 we issued an RFP for 2009 and 2010 OPV requirements.

Objective was to provide industry with a complete picture of the anticipated demand by the polio programme, not just demand channelled through UNICEF.

First time in many years that all Unicef demand could be handled through one tender.

Tender was concluded in August/September and awards communicated to manufacturers mid September.
Projected 2009-2010 OPV demand from GPEI, June 2008 and included in the UNICEF RFP document.

<table>
<thead>
<tr>
<th></th>
<th>2009</th>
<th>2010*</th>
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<tbody>
<tr>
<td></td>
<td>tOPV</td>
<td>mOPV1</td>
</tr>
<tr>
<td>UNICEF sub total</td>
<td>490.2</td>
<td>291.7</td>
</tr>
<tr>
<td>India</td>
<td>450.0</td>
<td>90.0</td>
</tr>
<tr>
<td>Pakistan</td>
<td>88.0</td>
<td>76.0</td>
</tr>
<tr>
<td>Total</td>
<td>1,028.2</td>
<td>457.7</td>
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- The requirement presented in the tender included Pakistan and India projected needs to ensure maximum visibility to industry.

- Awards made did not cover the full projected programme needs, and the awards were a conservative estimate of the expected demand through UNICEF based on confirmed programmatic requirement and confirmed country procurement strategies at the time of award.
UNICEF OPV awards 2009-2010

<table>
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<tbody>
<tr>
<td></td>
<td>tOPV</td>
<td>mOPV1</td>
<td>mOPV3</td>
<td>Total</td>
</tr>
<tr>
<td>Total</td>
<td>490.2</td>
<td>457.7</td>
<td>225.5</td>
<td>1,173.4</td>
</tr>
</tbody>
</table>

- At the time of award the unawarded quantities equal the tOPV requirements for India and Pakistan for both 2009 and 2010, the mOPV3 requirements for India and Pakistan for 2009 and ~20 million doses of mOPV1 for 2009 were reserved for later awards.

- For 2010 all known requirements were awarded, but as set forth in the tender the awarded quantities of mOPV were not specified by type in order to retain the flexibility to respond to programme needs. The specific OPV type required will be specified to the relevant manufacturers during 2009, in line with the required timelines.

- The awards made are not for any specified geographic destination.

- Since awards were made we anticipate that a larger part of the demand will be channelled through Unicef in 2009. Programme development and countries procurement strategy could add another 3-400 million doses of OPV for 2009 through Unicef.

- Drivers of this potential additional demand are developments in India and Pakistan, and the upcoming IEAG meeting will help clarify for the India 2009 needs. As demand is confirmed we will come back to manufacturers for additional availability.
Total OPV Forecast 2008/2009

- This reflects all demand expected through Unicef through first half 2009
- mOPV1 needs will be largely in the beginning of the year. Any additional potential awards for 2nd half of 2009.
Additional UNICEF polio tenders
Upcoming and potential tenders

• IPV for Palestine to be issued shortly.
  Estimated need is 230,000 doses throughout 2009

• Pending results of the clinical trials with bi-valent OPV
  - tender in Q1 2009??

• If requested by Government of India to procure IPV
  - tender in Q4 2008?
mOPV Stockpile – status and next steps

• Through the industry response to the RCI 2006-2007 manufacturers confirmed their principal interest in participating in a stockpile, and a number of defining technical constraints identified.

• The planned stockpile demand is 750 mio ds for each serotype = a total of 2.25 billion ds

Revised tender timeline following January 2008 WHA meeting:

• GAPIII revisions required following WHA Executive Board meeting in January 2008 (=> primary, secondary and tertiary safeguards)

• mOPV Stockpile tender delayed from December 2008 to December 2009

• Risk assessments of filling post-cessation to be conducted 6-12 months prior to tender issuance => to define manufacturer specific primary safeguard requirements

• Tentative timing of Stockpile demand 2012 - 2014 depending on epidemiological development
Thank you.
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