Polio tender overview

Industry Consultation
UNICEF Supply Division
25-26 January 2012
Presentation Overview

OPV Update: 2011

OPV Supply & Demand: 2012

Tender: strategic issues
  • including Polio (OPV & IPV) requirements 2013 & beyond
OPV Updates for 2011
India

Expect to make additional awards with final quantities similar to 2011
In 2011, UNICEF has procured over 1.6 billion doses of OPV, with value of $185 million, for delivery to 76 countries for routine immunization and SIAs

~85% of procurement for SIAs

*Data as of 25 October 2011
Factors influencing LTA utilisation for 2011

- Overall LTA utilisation of 92%
- tOPV & bOPV: under utilisation was due to non-availability of products
- mOPV3: low utilization due to use of bOPV. Manufacturers were informed of the shift in late 2010 in order to adjust production
OPV Funding Overview for SIA in 2011

- World Bank: 32%
- BMGF: 16%
- CDC: 16%
- JAPAN: 12%
- UNICEF RR: 11%
- Govt of Bangladesh: 4%
- CIDA: 2%
- Govt of Saudi Arabia: 1%
- GOOGLE: 1%
- Other donors: 3%
Update of OPV Supply & Demand for 2012
tOPV Supply & Demand to Dec 2012
tOPV Requirements 2012

• Based on current production schedules, sufficient tOPV to cover planned demand through August.

• However, supply will be very tight through Q3 2012. Any change in supply from manufacturers or an increase of demand will impact the Programme.

• Review OPV supply and demand to take place with Programme partners in early February; following which UNICEF may revert back to manufacturers for additional quantities in second half of 2012
bOPV Supply & Demand to Dec 2012
bOPV Requirements 2012

- Based on the current SIA plan, there is sufficient bOPV on contract to meet Programmatic requirements for 2012

- Supply availability will be tight throughout Q1 2012, requiring close management of changes in supply or demand

- Following review OPV situation with Programme partners in early February, UNICEF may revert back to manufacturers for additional quantities in 2H 2012

- Licensing of bOPV in Nigeria & Pakistan
  - Only one product is licensed in Pakistan
  - Two products (one with limited availability) licensed in Nigeria
  - This situation poses a substantial risk to the Programme and therefore we encourage all manufacturers to license their product in these countries
Tender: strategic issues
OPV: Tender Objectives

Ensuring sufficient quantities and flexibility between presentations in a timely manner as demand materializes

Affordable vaccines – achieving the lowest prices possible, within the overall framework of Vaccine Security.

• Additional evaluation criteria to achieve these objectives:
  • Type of coolant used for international shipments
    • To improve options for securing space on flights for delivery to difficult destination and/or for large campaigns and reduce the cost of air freight
  • Nearest cargo hub (in addition to nearest FCA point)
  • Alternative payment and/or contracting terms
OPV: Tender duration

Aligning with the Global Polio Eradication Initiative, “End Game Strategy” and key decision points

Most accurate quantity and product specific projections for the next 12-18 month period

Industry requests for volumes and visibility to secure supply and as important cost determinants

- Tender duration – under review
  - 2 year base period: 2013-2014, plus offers for longer durations which would be considered if they are of benefit to the programme and meet procurement objectives
  - 3 year duration (2013-2015) based on current products and demand forecasts
  - Other?
OPV: Invitee list and eligibility for award

• All manufacturers with WHO pre-qualified OPV as well as manufacturers intending to submit an OPV product for WHO pre-qualification.

• Only WHO pre-qualified products will be eligible for awards.

• Manufacturers are expected to undertake all reasonable efforts to ensure products are registered in the countries that require registration prior to use, and to keep UNICEF and WHO informed of the progress and development.

• Manufacturers are expected to inform UNICEF of activities undertaken and expected timelines in order to achieve pre-qualification.
OPV: products, quantities and countries

- OPV products to be tendered for:
  - tOPV in 10 & 20 dose vials
  - bOPV in 10 & 20 dose vials

- OPV type-specific requirements for 2013 and aggregate OPV for 2014 and beyond

- Demand for all countries expected to procure through UNICEF
  - not including India demand – expected to continue self-procurement
Current demand estimates, changes may occur depending on decision and timing for switch from tOPV to bOPV
Bulk OPV Stockpile

Tender covering stockpile of mOPV bulks through 2018 to support the polio endgame strategy
  • Tender quantity for the equivalent of 2.25 billion doses mOPV
  • Potential conversion to finished product from 2015

Awards made to two manufacturers for 1.2 billion doses of monovalent bulk

Any awards from 2015 will take into consideration stockpile bulk already awarded
OPV: Summary of demand

• Estimated quantities may be refined prior to issuing the tender

• Continued high demand for both tOPV & bOPV

• Timing of the switch from tOPV to bOPV will have an impact on type of demand

• Need to ensure flexibility and visibility:
  • 2013: OPV type specific request
  • 2014: aggregate OPV request
  • 2015 and beyond: aggregated OPV demand

• IPV demand will be *in addition to* OPV demand in the first years of accelerated IPV use
OPV Tender process: timelines

- 25-26 January: Industry consultation
- Mid-February: Feedback from manufacturers
- End February: Issuance of tender (5/6 weeks response time)
- Mid-April: Closing of tender
- Mid-April: Opening of tender (public opening)
- April -June:
  - Initial commercial review and identification of issues for clarification
  - Technical review of proposals by WHO, and follow-up with manufacturers for missing information, clarification of offers and technical requirements.
  - Clarification calls and meetings with manufacturers
  - Internal review and finalization of recommendations and approvals
- End June: Awards issued (6 months before required deliveries)
- January 2013: first supply
Critical programmatic decisions points that may affect polio vaccine supply and demand

Polio declared a “programmatic emergency for global public health” (WHO Executive Board, January 2012)

Emergency Action Plan (SAGE, April 2012)

Switch from tOPV to bOPV (SAGE working group, February 2012; SAGE April / November 2012)
  • Possible switch from 2014, but likely not affecting overall OPV demand until 2016-2018
  • Manufacturers will be requested to define the timelines needed to manage this switch

Standalone IPV anticipated to be the preferred product during the eradication and tOPV-bOPV switch phases; low cost hexavalent anticipated to be the preferred product in the 'post-OPV' period

OPV Cessation: 2017-2018
  • Anticipated larger scale use of hexavalent vaccine if available
Historically, UNICEF has procured limited quantities of IPV for routine use....

...however, demand is expected to increase significantly due to accelerated use of IPV in the eradication programme.
Programmatic demand for IPV – accelerated eradication plan

Quantities shown as full IM doses
Programmatic demand for IPV – tOPV to bOPV switch

In support of the switch from tOPV to bOPV.
Assumption: an affordable ID IPV available before universal introduction and use of IPV

Quantities are shown as full dose equivalents
Programmatic demand for IPV – Consolidated demand plus possible India demand

ID quantities are shown as full dose equivalents and based on 2 dose schedule
IPV: tender process

UNICEF to issue an initial tender to support the Emergency Action Plan
• IPV (IM full dose) covering campaign requirements in Q4 2012 – 2013/2014

Timelines:
• 25-26 January: Industry consultation
• **Early February: Feedback from manufacturers**
• Mid-February: Issuance of tender (4 weeks response time)
• Mid-March: Closing of tender
• Mid-March: Opening of tender
• March/April:
  • Initial commercial review and identification of issues for clarification
  • Technical review of proposals by WHO, and follow-up with manufacturers for missing information, clarification of offers and technical requirements.
  • Clarification calls and meetings with manufacturers
  • Internal review and finalization of recommendations and approvals
• **May: Awards issued**
• Q4 2012: first supply
IPV: summary

• Initial demand will be for stand alone IPV as part of the accelerated eradication plan
  • IM full dose for campaigns

• Universal use of IPV (in routine immunization) will depend on:
  • SAGE recommendation (April 2012) and World Health Assembly endorsement
  • ID IPV availability
  • Affordable pricing

• UNICEF expecting to issue additional tender for IPV in 2H 2012 covering ID IPV for use in routine immunization

• Longer term demand for IPV in routine anticipated to include substantial role for a low-cost hexavalent vaccine
Thank you