Tender for Bivalent Oral Polio Vaccines 2018 through to Cessation
November 16th 2016

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Presentation overview

- Background to and purpose of tender
- Procurement objectives
- Demand
- Duration and quantities for award
- Addressing the risks
- Tender timeline
Programmatic Context of bOPV Procurement

Objective 1
Detect and interrupt all poliovirus transmission
  • Secure availability of OPV including urgent delivery of the appropriate type of OPV to stop WPV transmission and interrupt cVDPV outbreaks.

2. Strengthen immunization systems and withdraw OPV
3. Containment and certification
4. Legacy planning

Current supply arrangements ending 2017
Purpose of Request for Proposal

- Seeking **comprehensive** and **innovative** proposals for the **sustained** and **uninterrupted** supply of **affordable** vaccines of **assured quality** to support the GPEI eradication program for the years **2018 through to cessation**, with final dates to be confirmed based on programmatic progress.

- Will work with selected manufacturers to establish **long-term arrangements** that best meet the **requirements of both parties** for ensuring that the requirements of countries, GPEI goals, and vaccine security objectives are met.
Procurement Objectives

1. Sustain sufficient supply of OPV to meet demand through polio eradication and OPV cessation
   - To secure the sustained, uninterrupted supply of vaccine of to meet planned programmatic requirements through eradication and final OPV cessation.
   - To secure the sustained, uninterrupted supply of polio vaccine in the event of delayed eradication and OPV cessation.
   - To secure sufficiently-sized buffer of supply to meet unplanned demand associated with outbreak response, and intensification of activities as defined by the Program.
Procurement Objectives

2. To guide the cessation of the OPV market in a responsible manner while maintaining affordability
   – To minimize risk of early market exits of manufacturers in the event of a delayed eradication and cessation, given the demand uncertainties for the outer years of tender.
   – To minimize risk of financial loss due to residual stocks with manufacturers associated with uncertainty in timelines and demand to balance affordability and market uncertainties.
A programme demand scenario and a UNICEF high demand scenario

Total demand varies between a maximum of 4.2 billion doses and 5.2 billion doses
Certainty of demand high for 2018-2019, with increasing uncertainty at this point in time towards 2022

- Supplementary Immunization Activities based on GPEI placeholder calendar
- Routine demand based on country forecasts for countries routinely procuring through UNICEF
- Rolling buffer – to be able to meet unplanned activities, to be replenished in case of use
- Certification 3 years after last polio case – cessation 12 months after certification
- Pre-cessation immunity boosting campaigns

<table>
<thead>
<tr>
<th>Requested quantities ('000 doses)</th>
<th>2018 I and II</th>
<th>2019 I and II</th>
<th>2020 I</th>
<th>2020 II</th>
<th>2021 I</th>
<th>2021 II</th>
<th>2022 I</th>
<th>2022 II</th>
<th>Total w/o buffer</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIA demand</td>
<td>680,615</td>
<td>680,615</td>
<td>392,615</td>
<td>680,615</td>
<td>570,960</td>
<td>392,615</td>
<td>570,960</td>
<td>2,324,805</td>
<td>3,005,420</td>
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<tr>
<td>Routine demand (20 ds)</td>
<td>200,000</td>
<td>200,000</td>
<td>200,000</td>
<td>100,000</td>
<td>200,000</td>
<td>100,000</td>
<td>700,000</td>
<td>900,000</td>
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</tr>
<tr>
<td>Routine demand (10 ds)</td>
<td>60,000</td>
<td>60,000</td>
<td>60,000</td>
<td>30,000</td>
<td>60,000</td>
<td>30,000</td>
<td>210,000</td>
<td>270,000</td>
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<tr>
<td>Total without buffer</td>
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<td>652,615</td>
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<td>700,960</td>
<td>652,615</td>
<td>700,960</td>
<td>3,234,805</td>
<td>4,175,420</td>
</tr>
<tr>
<td>Rolling buffer I and II, max.</td>
<td>200,000</td>
<td>200,000</td>
<td>200,000</td>
<td>200,000</td>
<td>200,000</td>
<td>200,000</td>
<td>0-1,000,000</td>
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Proposals for Products not yet pre-qualified

Detailed plan on timeline to obtain WHO pre-qualification, product and plans for manufacturing and licensing required

- Product Development: Status and plans, including source of bulk antigens to be used;
- Clinical Trials: Trials conducted so far and planned, with timelines;
- National Regulatory Registration: Status and plans for registration, including NRA that would be responsible for release of finished product and planned product presentations; and
- File submission to WHO: Status and plans.
## What is new and different? How to address it?

<table>
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<tr>
<th>Challenges</th>
<th>Mitigation Options</th>
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| Tender covers demand through to cessation, with timing dependent on WPV interruption | • Tender for demand through to 2021, with an option to extend to 2022?  
• Tender through 2022?  
• To be extended further, if supplier agrees |
| Securing supply for outbreaks and unplanned activities                     | • Establishing a rolling buffer across suppliers, to be replenished upon use      |
| Risks of residual stocks at time of cessation                              | • Close monitoring and management of awards and LTAs by UNICEF (~tOPV)  
• Demand updates to be provided every 6 months to industry                  |
| Price setting                                                              | • Option to revisit conditions and arrangements, if extended beyond 2022  
• Co-sharing of risks by GPEI (~tOPV)                                       |
Tender timeline

• Issuance of RFP – 3 weeks post industry consultation
• Written enquiries to aghazieh@unicef.org, responses to be provided to all invitees and posted on UNICEF’s website
• Sealed proposals to be submitted within 6 weeks (?), in two copies, of which one is required to be original
• Review of mandatory requirements (WHO/UNICEF) and evaluation, 2 weeks after submission
• Clarifications and negotiations with suppliers, as required
• Presentation of general principles for award to GPEI
• Award letters to be issued – likely end Q2 2017
• First deliveries January 2018
In summary

• bOPV tender to be issued end November, with supply start in January 2018
• Response lead time 6 weeks (?)
• Supply through to OPV cessation 2021/2022, and in case of a potential extension
• Good visibility on near term demand, with biannual updates to be provided to industry
• Key objectives: securing supply through to cessation at affordable prices; needing flexibility and commitment from manufacturers to continue to supply through to cessation
Questions to industry

Forecast to tender for
• Through 2021?
• Through 2022?

Response lead time
• 6 weeks?
• Other duration

Any other questions?