Current OPV Supply & Outlook

UNICEF Supply Division

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1. Summary

- The tender for OPV supply in 2013-2017 resulted in Long Term Arrangements (LTAs) with six manufacturers to supply 4.7 billion doses.
- A challenging supply period during Q1 and Q2 2013 has contributed to a constrained supply situation for 2013, with little room for flexibility for changes in planned supply delivery schedules and requirements.
- The Global Polio Eradication Initiative’s (GPEI) “End Game” strategy to stop polio transmission in all remaining endemic and high risk countries comprises key objectives of replacing tOPV with bOPV by 2016 and introducing Inactivated Polio Vaccine (IPV) as a booster into all national immunisation programmes by end 2015.
- Due to the short timeline of IPV introduction, and the potential risk of delay, UNICEF will work with all stakeholders to ensure that sufficient quantities of OPV are available to meet programmatic needs, in parallel to working to secure sufficient quantities of affordable IPV.

2. Background & Procurement History

UNICEF procures OPV on behalf of national governments, GPEI and UNICEF programmes for both routine immunisation and supplementary immunisation activities (SIAs). Since 2000, UNICEF OPV procurement has averaged 1.8 billion doses annually. However, UNICEF procurement has declined since 2010, reaching 1.3 billion doses in 2012. The decline is principally a result of India’s transition to self-procurement of OPV in Q4 2010.

Polio vaccines are manufactured in several different formulations:

- tOPV: a trivalent oral polio vaccine consisting of the live, attenuated poliovirus strains of all three wild poliovirus types 1, 2 and 3, used in both routine and SIA activities. tOPV comes in both 10-dose and 20-dose vial presentations.
- mOPV1, mOPV2 and mOPV3: monovalent attenuated oral polio vaccines made up of wild poliovirus strains 1, 2 or 3, respectively. mOPV comes in a 20-dose vial presentation.
- bOPV: a bivalent oral polio vaccine made up of the two strains type 1 and 3. bOPV does not protect against type 2. It is used only for SIA activities and comes in a 20-dose vial presentation.
- In addition, UNICEF procures a small quantity of IPV for a limited number of countries in support of routine immunisation programmes. IPV provides serum immunity to all three types of poliovirus, resulting in protection against paralytic poliomyelitis.

Since GPEI’s 1988 launch, the number of polio cases has dropped from 350,000 to 223 cases in 2012. Failure to vaccinate could result in a retrenchment in global cases reaching 200,000 new cases.

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annually within 10 years. Therefore, continued availability of appropriate polio vaccine is critical to ensuring programmatic success.

Figure 1 Supply History and Breakdown of OPV Vaccines and WAP Trend

GPEI launched the “End Game Strategic Plan 2013-2018” at the World Health Assembly in May 2013. The comprehensive plan focuses on eliminating both wild and vaccine-derived polio incidence through strengthened routine immunisation systems, a gradual replacement of routine OPV use with IPV vaccine, and enhanced risk mitigation and contingency plans. GPEI’s strategy specifically includes several points that directly impact polio vaccine supply, notably:

- Replacement of tOPV with bOPV by 2016, subject to cessation of transmission of circulating vaccine derived polio virus type 2 (cVDPV2) during the previous 12-month period.
- IPV introduction into the routine immunisation programmes of approximately 130 countries by the end of 2015, initially as a booster vaccine (following 2 doses of OPV prime) to routine vaccination programmes.
- bOPV withdrawal after four years following the final case report. IPV will remain the polio vaccine of choice, replacing OPV in routine immunisation for 5 years post-OPV cessation.
- Establishment of a strategic contingency stockpile of OPV bulk of all three poliovirus strains for emergency and in support WHO’s post-eradication immunisation policy.

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The current market is experiencing continued high demand in the context of a less flexible supply base, reconfirming the need for adequate planning and providing visibility on supply and demand to countries, programmatic partners and manufacturers. As a result, GPEI partners, including UNICEF, are actively working with manufacturers to plan and ensure sufficient OPV supply to respond to new demands, the transition from tOPV to bOPV by 2016, adequate supplier flexibility, and available manufacturing capacity in order to support polio eradication efforts.

3.1 Projected Demand

For 2013-2014, the projected demand for OPV was expected to remain at 2012 levels of 1.3 billion doses, at a minimum. However, demand for OPV, particularly bOPV, has increased on account of intensified campaign activity in endemic and priority countries. The total quantities to be supplied during 2013 will reach in excess of 1.5 billion doses.

Figure 2 Quarterly Forecast of OPV Supply for 2013 through UNICEF

UNICEF OPV procurement for Q1 2013 was less than the original forecasts of 340 million by 50 million doses. However, Q2 2013 demand exceeded original forecasts by 150 million doses. Increased demand from Pakistan and Nigeria drove this increase. For 2015-2018, GPEI projects declining demand which is contingent on stopping transmission of Wild Polio Virus (WPV) and cVDPV in endemic and priority countries. The decline in demand will also depend upon the extent countries successfully transition to a 3-dose IPV schedule, replacing OPV in their routine immunisation programmes.

3.2 Supply and Capacity

Upon tender conclusion in 2012, UNICEF made awards to six manufacturers totalling 4.7 billion doses and a value of US$658 million.

While overall forecasted demand was met through the awards, during evaluation of the 2013-2017 tender, there was a potential for an OPV supply shortfall of 300 million doses for 1H 2013. UNICEF worked with manufacturers to accelerate production plans in addition to closely monitoring in-country inventory. Additionally, WHO fast-tracked the pre-qualification of Serum Institute of India

\[\text{Data as of 30/06/2013}\]
(SII), a new OPV supplier, to help manage the shortfall. While these actions addressed the most acute supply challenges, delivery schedules will remain very tight throughout 2013, and thereby limiting potential accommodation of un-forecasted demand.

Figure 3 UNICEF Awards for the 2013-2017 OPV Tender

<table>
<thead>
<tr>
<th>Company</th>
<th>US$ value</th>
<th>Duration</th>
<th>Vaccine</th>
<th>Vials</th>
<th>Present.</th>
<th>Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bio Farma</td>
<td>58,382,500</td>
<td>LTA - 4 years</td>
<td>tOPV / bOPV</td>
<td>23,750,000</td>
<td>20ds</td>
<td>475,000,000</td>
</tr>
<tr>
<td>Haffkine Bio-Pharm</td>
<td>34,485,000</td>
<td>LTA - 2 years</td>
<td>tOPV</td>
<td>12,100,000</td>
<td>20ds</td>
<td>242,000,000</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>235,413,382</td>
<td>LTA - 5 years</td>
<td>tOPV / bOPV</td>
<td>68,550,000</td>
<td>20ds</td>
<td>1,371,000,000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>tOPV / bOPV</td>
<td>14,600,000</td>
<td>10ds</td>
<td>146,000,000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>mOPV</td>
<td>300,000</td>
<td>20ds</td>
<td>6,000,000</td>
</tr>
<tr>
<td>Novartis</td>
<td>3,867,500</td>
<td>LTA - 1 year</td>
<td>tOPV</td>
<td>1,750,000</td>
<td>20ds</td>
<td>35,000,000</td>
</tr>
<tr>
<td>Sanofi Pasteur</td>
<td>245,300,000</td>
<td>LTA - 5 years</td>
<td>tOPV / bOPV</td>
<td>78,850,000</td>
<td>20ds</td>
<td>1,577,000,000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>tOPV / bOPV</td>
<td>9,400,000</td>
<td>10ds</td>
<td>94,000,000</td>
</tr>
<tr>
<td>Serum Institute of India</td>
<td>80,100,000</td>
<td>LTA - 4 years</td>
<td>bOPV</td>
<td>37,500,000</td>
<td>20ds</td>
<td>750,000,000</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division.

- Bio Farma (Indonesia), GlaxoSmithKline (GSK) (UK) and Sanofi Pasteur (France) are the only OPV bulk manufacturers.
- Haffkine Bio-Pharm (India) and SII are the only manufacturers to have capacity to accommodate additional demand for this year.
- Novartis (Switzerland) has stopped their manufacture of OPV. They are currently concluding the supply and distribution of remaining stocks during 2013, and possibly 2014.
- Two manufacturers’ loss of WHO prequalification in 2011 has decreased supply availability and has limited flexibility to respond to urgent changes.
- 5% of the awarded quantities of OPV are in 10-dose vial presentations. One of the two manufacturers of 10-dose vials is experiencing challenges in delivering OPV, and the other is not able to cover the ensuing shortfall. As a result, there will be a shortage of OPV in 10-dose vial presentations adding further pressure on the supply of substitute 20-dose vial presentations.

The Weighted Average Price (WAP) per dose of OPV has steadily increased from 2000 to 2008, with an average price of approximately US$0.14 per dose recently. Pricing has been relatively stable over the last few years though despite changes to OPV formulations entering the market (see Figure 1). The pricing of tOPV has increased as supply and demand has decreased in favour of bOPV. The price of bOPV slightly decreased and has remained stable since introduction.

4. Issues / Challenges

- The supply constraints in the market are compounded by the restrictive issuance of licenses to manufacturers by countries in need of OPV. Pakistan and Nigeria represent 60% of the demand for OPV for Q1 2013. However, only GSK and Sanofi have licences to supply Pakistan, and only GSK, Sanofi and Bio Farma are licensed to supply Nigeria. SII and Haffkine are not licensed to supply either Pakistan or Nigeria. However, both Haffkine and SII have been granted temporary waivers to supply Nigeria for this year.
- From June 2013, demand will increase for bOPV throughout the second half of the year as a result of vaccination campaigns primarily in Nigeria and Pakistan.
• Additional work is required to obtain wide scale licensure to manufacturers of Sabin strain IPV. The vaccine is required for the certification/containment stage of the GPEI strategy.
• Funding availability issues, particularly in endemic countries, resulted in some delays in procurement action, consequently putting increased pressure on supply chains from manufacturers and international transportation to receipt and in-country distribution to meet SIA requirements. In addition, increased exposure to financial risk and the need to divert funding to cover some of these gaps has had a programmatic effect on the sources from which they were taken.

5. Steps Forward

• In order to meet demand, UNICEF and partners will continue to review and map all vaccine requirements by type in order to plan additional supply, if necessary. The supply for some non-risk countries may subsequently shift to later in the year. A change in choice of vaccine from bOPV to tOPV will also be sought for countries with cVDPV/VDPV.
• UNICEF will award additional doses of tOPV and bOPV to increase availability in accordance with prevailing epidemiological data in endemic and high-risk countries.
• UNICEF and partners will continue to encourage endemic and high-risk countries to license or grant temporary import waivers to WHO pre-qualified manufacturers with a capacity to supply OPV and IPV. All manufacturers should have the capacity to supply additional needs over the next four years.
• In order to ensure SIA requirements are met, additional financing solutions will be sought for managing funding and timing gaps encountered.
• To ensure maximum efficiency in the utilisation of all resources, UNICEF will also support efforts to address vaccine management and immunisation supply chain challenges in countries.

For further questions or additional information, please contact:

Meredith Shirey  Jennifer Rubin  Aadrian Sullivan  
Chief, Vaccine Centre  Contracts Manager  Information Management  
UNICEF Supply Division  UNICEF Supply Division  UNICEF Supply Division  
+45 3527 3033  +45 3527 3149  +45 3527 3048  
mshirey@unicef.org  jrubin@unicef.org  asullivan@unicef.org

Information notes can be found: http://www.unicef.org/supply/index_54214.html