Current IPV Supply, Recent Tender Results & Outlook for the Future

2 November 2012
Overview of Current IPV Supply & Recent Tender Results

IPV Market: Recent Tender Developments

In March 2012, UNICEF issued a Request-for-Proposal (RFP) to solicit offers for full-dose inactivated polio virus (IPV) vaccine for intramuscular use, in support of polio eradication efforts in high-risk areas in Nigeria and Pakistan, as well as to cover routine requirements in Lebanon and the Occupied Palestinian Territories (oPT) for 2012 and 2013.

The original RFP called for:
- Supplementary Immunization Activities (SIAs) in Nigeria and Pakistan: 8 Mds of IPV for campaigns starting in Q4 2012 and 15 Mds for 2013.
- Routine Requirements: 300,000 and 350,000 doses of IPV in 2012 and 2013, respectively for oPT and Lebanon.

UNICEF received offers from 6 suppliers: 4 offering WHO-prequalified IPV and 2 offering non-prequalified IPV. After the RFP issuance and receipt of offers, the WHO Polio Programme indicated that the requirements for the SIAs in Nigeria and Pakistan would be needed for 2013-2014 at the earliest, and probably at substantially lower quantities. In addition, Lebanon cancelled their 2012 order. The final awarded quantity was 600,000 doses to be used in routine vaccination during 2012-2013.

The results of the tender and estimates of current capacity suggest manufacturers’ willingness to increase production if presented with high visibility of demand.

Supply and Production per Tender Responses

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Product</th>
<th>PQ</th>
<th>Expected Capacity</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSK</td>
<td>1 ds</td>
<td>Y</td>
<td>N/A “large enough”</td>
<td>WHO-PQ product with significant capacity; IPV standalone product will be limited in favour of hexavalent and other combination products</td>
</tr>
<tr>
<td>Sanofi</td>
<td>10 ds</td>
<td>Y</td>
<td>Bulk: 100 Mds → 300 Mds</td>
<td>In process of expansion</td>
</tr>
<tr>
<td>Staten Serum Institute</td>
<td>1 ds</td>
<td>Y</td>
<td>2 Mds → 10 Mds</td>
<td>Can be increased with additional equipment</td>
</tr>
<tr>
<td>NVI(1)</td>
<td>1 ds</td>
<td>Y</td>
<td>20 Mds bulk</td>
<td>Capacity represents current availability</td>
</tr>
<tr>
<td>Panacea</td>
<td>1 ds</td>
<td>N</td>
<td>44 Mds (annual)</td>
<td>Baddi facility (NVI bulk); vial and pre-filled syringe</td>
</tr>
<tr>
<td>SII</td>
<td>1 ds</td>
<td>N</td>
<td>20 Mds (annual)</td>
<td>Recent acquisition demonstrates commitment to IPV</td>
</tr>
</tbody>
</table>

(1) Bilthoven Biologicals (privatized continuation of NVI production activity) acquired by SII in June 2012. NVI and SII capacity refers to the same capacity.
Results for 2012 IPV Tender Covering 4Q2012 and 2013 – Offered Quantities & Prices

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>GSK</td>
<td>1 ds</td>
<td>650,000</td>
<td>$4.14</td>
<td>from routine</td>
<td>$4.14</td>
</tr>
<tr>
<td>Sanofi</td>
<td>10 ds</td>
<td>650,000</td>
<td>$2.25 - $2.70</td>
<td>23,000,000</td>
<td>$2.25 - $2.70</td>
</tr>
<tr>
<td>Staten Serum Institute</td>
<td>1 ds</td>
<td>400,000</td>
<td>$5.70</td>
<td>1,100,000</td>
<td>$5.70</td>
</tr>
<tr>
<td>NVI(1)</td>
<td>1 ds</td>
<td>604,000</td>
<td>€2.50</td>
<td>2,000,000</td>
<td>€2.50</td>
</tr>
<tr>
<td>Panacea</td>
<td>1 ds vial</td>
<td>350,000</td>
<td>$3.55</td>
<td>3,150,000</td>
<td>$3.55</td>
</tr>
<tr>
<td></td>
<td>1 ds PFS</td>
<td>650,000</td>
<td>$4.35</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>SII</td>
<td>1 ds</td>
<td>--</td>
<td>--</td>
<td>11,000,000</td>
<td>€2.00 - €2.50</td>
</tr>
</tbody>
</table>

(1) Bilthoven Biologics (privatized continuation of NVI production activity) acquired by SII in June 2012.
(2) If annual purchase volumes are greater than 15 Mds, price would be $2.25.
(3) Total offered quantity over both years and routine and SIA activities is 1,100,000 doses.
(4) Price decreases of 5% for every 5 Mds procured annually.
(5) Based upon discussions, depending upon volumes, could offer a €0.50 discount to offered €2.50.

UNICEF’s Perspective

UNICEF has data substantiating that the results of the 2012 IPV tender are not indicative of the long-term market and pricing trajectories:

- Volumes were small, especially when compared to current existing capacity. “One-off” demand which was not underpinned by routine policy certainty was also likely a key reason that prices were not lower.
- The full detailed responses demonstrate that with increased volume, manufacturers are willing to offer price discounts. Increased volume correlated with lower price and three of the manufacturers specifically offered volume-based incentives for lower pricing described above.
- Manufacturers have signaled that with increased policy certainty (on both IPV and specifically on an Intradermal modality) improving regulatory and demand visibility, they would be able to adjust price accordingly. In that context of increased policy certainty, subsequent conversations have explicitly re-confirmed the value vis-à-vis lower pricing that could be generated in return for volume commitments.
- Recent tender responses do not contemplate the added benefit of fractional dosing which transforms single-dose vials into multi-dose vials, thereby providing a significantly improved cost-effective presentation, while also enabling the optimization of production capacity.

Availability of a low-cost IPV option as a key component of the three-pronged polio end-game strategy:

- Supply capacity is already in the process of being increased during next few years to meet estimates of global demand (WHO):
  - Wild-Virus Eradication (through Whole-Dose IPV): 10-20 Mds annually for 1-2 years.
• tOPV-bOPV Switch (through IM/ID IPV): 100+ Mds annually for 3-4 years.
• Post bOPV Cessation (through IM/ID IPV or hexavalent): 200+ Mds annually for > 6 years.
  o Routine use remains highly sensitive to the availability of a low-cost option. With substantially increased demand and adoption of an ID-fractional delivery modality, anecdotal data that UNICEF has collected suggests that pricing of US$1.00 per dose or lower could be feasible over the medium-to-long term.1 We note that a “<US$1” per dose price could already be achievable with fractional dosing of current low-volume pricing.
  o Clear policy from advisory bodies is needed to build the sustained demand required for a ramp-up of production; clear guidance from regulatory authorities on regulatory pathways is needed to plan development.

The broader Polio End-Game Strategy discussions and policy development in addition to continued stakeholder engagement are likely to maintain supplier interest in the market for a low-cost product:
  o Manufacturers are already in the process of materially increasing bulk and fill/finish capacity. (e.g., Sanofi Pasteur IPV volume capacity could be sufficient to supply all countries currently using OPV on a 1-dose IPV IM route schedule).
  o One of the bulk manufacturers at the time of the original tender was discussing the opportunity of providing bulk to an Indian manufacturer to provide both 1-dose and 10-dose formulations.

Industry comments from tender responses describing commitment to lower pricing:
  o European Manufacturer: “… is considering intradermal IPV as a low cost approach to ensure vaccine affordability for global implementation during the polio pre and post eradication eras.”
  o Indian Manufacturer: “Regarding our plans for intradermal IPV we remain interested to enter into the product development in line to the recommendations of WHO.”
  o European Manufacturer: “… would like to engage in a dialogue with the WHO / UNICEF with regard to the possibility to obtain approval of producing and supply its WHO prequalified IPV Vaccine in a two-dose vial without preservative as such approval would greatly influence on [its] available capacity (and not least on pricing as well).”
  o European Manufacturer: “We are looking at transferring to our… subsidiary some manufacturing activities to reduce production costs and therefore improve the affordability of our IPV vaccine in the long term.”

Although work is currently being done to improve hexavalent formulations, commentary from suppliers has tempered expectations regarding the near-to-medium term technical feasibility (and affordability) of a hexavalent product, thereby highlighting the importance of a standalone IM/ID product. It is also noted that fractional dosing has a number of product development and licensing issues that still need to be overcome.

1As an example, Serum Institute of India (SII) has provided written communication to the WHO Director-General indicating that their revised current offer is €1.25 for single dose (€0.90 for multi-dose). With an effective adjuvant or ID pathway, they would be able to offer <$1.00.
For further questions or additional information, please contact:

Meredith Shirey
Chief, Vaccine Centre
UNICEF Supply Division
+45 3527 3033
mshirey@unicef.org

Jonathan M. Weiss
Manager, Innovative Finance
UNICEF Supply Division
+45 3527 3021
jmweiss@unicef.org

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