BCG Vaccine: Current Supply & Demand Outlook

UNICEF Supply Division

September 2013
1. Summary

- The tender concluded in 2012 for the supply of BCG for 2013-2015 resulted in Long Term Arrangements (LTAs) with four manufacturers for the supply of 348 million doses.
- Two manufacturers’ supply capacity for 2013 has temporarily reduced, while incremental demand has increased total 2013 requirements by an additional 15 million doses.
- The remaining manufacturers have increased supply to UNICEF to make up for the original deficit. However, a shortfall of 14 million doses still exists against revised forecast requirements.
- As a result, BCG availability through UNICEF is anticipated to remain tight through Q1/Q2 2014.
- UNICEF is consequently working closely with countries and manufacturers to ensure an equitable distribution of all available doses and adjust shipment plans.
- Reduced availability is expected to be temporary, with an anticipated return to full and stable supply volumes during Q2/Q3 2014.

2. Background & Procurement History

An estimated 8.7 million and 1.4 million people annually suffer and die, respectively, from Tuberculosis (TB), mainly in low and middle income countries. TB is also among the top three causes of mortality in women aged 15 to 44.\(^1\) BCG vaccine provides protection against TB and is particularly effective against disseminated (miliary) TB in children.\(^2\) WHO recommends BCG vaccination for infants as soon as possible after birth, particularly in countries with a high TB burden.\(^3\) BCG vaccine is currently available from 4 manufacturers.

Figure 1 WHO Prequalified BCG Manufacturers

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>WHO Prequalif.</th>
<th>Formul.</th>
<th>Schedule</th>
<th>Vial</th>
<th>Shelf Life</th>
<th>Cold Chain Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervax Ltd (Canada)</td>
<td>1991</td>
<td>Lyophilised</td>
<td>1 ds</td>
<td>20 ds</td>
<td>36 months</td>
<td>1.125 cm³ / ds</td>
</tr>
<tr>
<td>Japan BCG Laboratory</td>
<td>1987</td>
<td>Lyophilised</td>
<td>1 ds</td>
<td>20 ds</td>
<td>24 months</td>
<td>2.362 cm³ / ds</td>
</tr>
<tr>
<td>Serum Institute of India Ltd</td>
<td>2003</td>
<td>Lyophilised</td>
<td>1 ds</td>
<td>20 ds</td>
<td>24 months</td>
<td>2.611 cm³ / ds</td>
</tr>
<tr>
<td>Statens Serum Institute (Denmark)</td>
<td>1987</td>
<td>Lyophilised</td>
<td>1 ds</td>
<td>20 ds</td>
<td>12-24 months</td>
<td>1.330 cm³ / ds</td>
</tr>
</tbody>
</table>

Source: WHO.

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BCG has been part of the Expanded Programme of Immunisation (EPI) vaccination schedule since 1974, and has historically had a solid supply base. Since 1996, the demand for BCG through UNICEF has averaged 110 million doses a year. Vaccine Weighted Average Price (WAP) has also remained stable at around $0.08 per dose since 2004 (Figure 2).

Figure 2 BCG Supply through UNICEF and Demand Forecast through to 2015

Source: UNICEF Supply Division.

3. Current Market Situation

3.1. Demand

UNICEF’s original forecast requirement for 2013 was 115 million doses. As of the end of August 2013, UNICEF has procured more than 100 million doses for 64 countries, and now anticipates a revised 2013 requirement of 130 million doses. A current balance of 30 million doses of BCG is forecast for Q3/Q4 2013.

3.2. Supplier Base


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Figure 3 UNICEF Original Quantities Awarded for 2013

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Manufacturer</th>
<th>Value</th>
<th>Presentation</th>
<th>Vials</th>
<th>Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>Intervax Ltd</td>
<td>$2,145,000</td>
<td>20ds</td>
<td>1,500,000</td>
<td>30,000,000</td>
</tr>
<tr>
<td>BCG</td>
<td>Japan BCG Laboratory</td>
<td>$2,740,000</td>
<td>20ds</td>
<td>1,000,000</td>
<td>20,000,000</td>
</tr>
<tr>
<td>BCG</td>
<td>Serum Institute of India Ltd</td>
<td>$3,437,500</td>
<td>20ds</td>
<td>2,750,000</td>
<td>55,000,000</td>
</tr>
<tr>
<td>BCG</td>
<td>Statens Serum Institute</td>
<td>$1,495,000</td>
<td>20ds</td>
<td>500,000</td>
<td>10,000,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>$9,817,500</strong></td>
<td></td>
<td><strong>5,750,000</strong></td>
<td><strong>115,000,000</strong></td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division.

However, two manufacturers have reduced their 2013 supply availability by 24 million doses. UNICEF has since secured additional supply from the remaining suppliers, mitigating the reduced supply availability. Therefore the total expected availability for 2013 is 116 million doses.

4. Issues / Challenges

- Taking into consideration the changes in supply availability, a shortfall of 14 million doses remains against the revised 2013 requirements of 130 million doses. This will result in tight availability during the Q3/Q4 2013 and possibly into Q1/Q2 2014.
- UNICEF is working with countries on delivery plans and schedules to prevent stock-outs and interruptions to immunisation programmes.
- Affected countries have also been requested to review vaccine stock levels in order to support global supply management during the next 3 quarters.

5. Steps Forward

- UNICEF will share new shipment plans with affected countries. UNICEF has also followed up with those countries that have not yet placed orders, but who anticipate low BCG vaccine stock levels.
- UNICEF has requested manufacturers with supply available for 2014 to advance available quantities into Q1 2014 if possible.
- UNICEF continues to closely monitor the status at the suppliers with reduced capacity to assess whether the reduced capacity will extend into (or beyond) Q3 2014.

For further questions or additional information, please contact:

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Information notes can be found: [http://www.unicef.org/supply/index_54214.html](http://www.unicef.org/supply/index_54214.html).