BCG Vaccine: Current Supply & Demand Outlook

UNICEF Supply Division

August 2014
Bacillus Calmette-Guérin (BCG) Vaccine
Supply & Demand Update – August 2014

This update provides new information on BCG supply availability, increased country demand, and continued supply constraints anticipated to last through 2Q 2015.

A more recent note covering BCG exists. Please visit [http://www.unicef.org/supply/index_54214.html](http://www.unicef.org/supply/index_54214.html)

1. Summary

- Current BCG supply through UNICEF will not meet all country requirements for the remainder of 2014 and into 2015. Incremental unforecasted requests from some countries including large Middle Income Countries (MICs) which typically self-procure and a backlog of previous demand have contributed to increased demand.
- Technical difficulties affecting vaccine production previously reduced the production capacity of two manufacturers during 2H 2013 through 1Q 2014. However, the other two remaining manufacturers increased their supply to accommodate the shortfall. UNICEF allocated available vaccine on a priority basis, split 2013 shipment orders over 2013-2014 and secured an additional 3.2 million doses offered by one manufacturer in February 2014 to maximise supply.
- The two constrained manufacturers have since resolved their technical difficulties and are increasing production to return to previous levels. However, backlog from 2013 and the new procurement requests exceed available supply, and will again contribute to tight supply through (at least) 2Q 2015.
- UNICEF is working closely with countries and manufacturers to ensure an equitable distribution of all available doses on a priority basis and adjusted shipment plans. The current BCG tender period expires in December 2015. A new tender will be issued during 1H 2015.

2. Background & Procurement History

UNICEF’s previous September 2013 BCG Supply Update provides a general market background and update on 2013 supply. The note describes BCG vaccine supply constraints and the measures taken to manage supply availability through 1Q 2014, as a result of technical difficulties reducing manufacturer production capacity. Supply is now returning to original production expectations.

Tabel 1 WHO Prequalified BCG Manufacturers

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>WHO PQ</th>
<th>Formul.</th>
<th>Sched.</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</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</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</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</td>
</tr>
</tbody>
</table>

Source: WHO.
* Note: BCG vaccine procured from Intervax is manufactured by BB-NCIPD Ltd (Bulgaria).

During 2013, UNICEF procured 126 million doses, with 118 million doses delivered during the year, and 8 million delivered in 1Q 2014.
3. Current Market Situation

3.1. Demand

The current baseline UNICEF demand is 123 million doses a year. UNICEF had originally anticipated procuring ~123 million doses during 2014 for 67 countries. However, the backlog of demand from 2013 in addition to new demand from some large countries in the Middle East and South East Asia, including some MICs which traditionally self-procure BCG vaccine (Egypt, Nigeria and Pakistan), have increased the 2014 demand forecast through UNICEF by 24 million to reach 147.5 million doses (Figure 1), exceeding 2014 availability of 120 million.

Figure 1 UNICEF BCG Demand Forecast through 2015

Source: UNICEF Supply Division.

3.2. Supply

Two manufacturers had experienced technical difficulties during 2H 2013 through 1Q 2014, reducing 2013 supply by 26 million doses (60% of their collective awarded supply). The two remaining vaccine manufacturers increased their respective allocation to UNICEF, making up any shortfall, and increasing aggregate supply by an additional 3 million doses (Table 2).

Table 2 Manufacturer Awarded Supply versus 2013 Procured and Delivered BCG Quantities

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Originally Awarded 2013 Supply</th>
<th>Production Change</th>
<th>%</th>
<th>Procured Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervax Ltd</td>
<td>30,000,000</td>
<td>14,380,000</td>
<td>48%</td>
<td>44,380,000</td>
</tr>
<tr>
<td>Japan BCG Laboratory</td>
<td>20,000,000</td>
<td>14,300,000</td>
<td>72%</td>
<td>34,300,000</td>
</tr>
<tr>
<td>Serum Institute of India Ltd</td>
<td>55,000,000</td>
<td>-17,074,000</td>
<td>-31%</td>
<td>37,926,000</td>
</tr>
<tr>
<td>Statens Serum Institute</td>
<td>10,000,000</td>
<td>-8,623,000</td>
<td>-86%</td>
<td>1,377,000</td>
</tr>
<tr>
<td>Total</td>
<td>115,000,000</td>
<td>2,983,000</td>
<td>3%</td>
<td>117,983,000</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division.
For 2014, an extra 3.2 million doses were awarded to one manufacturer, maximising all vaccine availability, and increasing 2014 awarded supply from 115 million doses to 123.2 million doses (Table 3). However, previous limitations in one manufacturer’s supply may limit actual 2014 availability to reach 120 million doses.

Table 3 UNICEF Original Quantities Awarded for 2013-2015

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>2013 (Original)</th>
<th>2014 (Original)</th>
<th>2014 Prices</th>
<th>Add’l Awards (Feb 2014)</th>
<th>2014 (Current)</th>
<th>2015</th>
<th>2015 Prices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervax Ltd</td>
<td>30,000,000</td>
<td>34,000,000</td>
<td>$0.0715</td>
<td>+ 3,183,000</td>
<td>37,183,000</td>
<td>36,000,000</td>
<td>$0.0748</td>
</tr>
<tr>
<td>Japan BCG Lab.</td>
<td>20,000,000</td>
<td>32,000,000</td>
<td>$0.1370</td>
<td>--</td>
<td>32,000,000</td>
<td>32,000,000</td>
<td>$0.1370</td>
</tr>
<tr>
<td>SII*</td>
<td>55,000,000</td>
<td>44,000,000</td>
<td>$0.0625</td>
<td>--</td>
<td>44,000,000</td>
<td>45,000,000</td>
<td>$0.0680</td>
</tr>
<tr>
<td>SSI**</td>
<td>10,000,000</td>
<td>10,000,000</td>
<td>$0.1495</td>
<td>--</td>
<td>10,000,000</td>
<td>10,000,000</td>
<td>$0.1570</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>115,000,000</td>
<td>123,183,000</td>
<td>+ 3,183,000</td>
<td></td>
<td>118,000,000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division.  
* Note: Serum Institute of India Ltd  
** Note: Statens Serum Institute

Despite efforts to normalise and increase overall manufacturer vaccine production capacity during 2Q 2014, supply will not be able to meet revised 2014 forecast requirements of 147.5 million doses (Figure 1). 27 million doses from 2014 demand have been postponed for delivery to 2015 (Figure 2). UNICEF will allocate requirements on a priority basis to countries at risk of Expanded Program on Immunization (EPI) interruptions, however, supply will remain constrained through at least 2Q 2015 and may result in a possible cumulative shortfall of 39 million doses during 2015.

Figure 2 2014-2015 UNICEF BCG Supply Availability (and Timing) versus Demand

BCG vaccine availability through UNICEF may be further constrained as no new manufacturers are anticipated to enter the BCG market with WHO prequalified vaccine, and one of the existing contracted manufacturers (Statens Serum Institute) has announced its intention to sell its BCG vaccine manufacturing division.
4. Issues / Challenges

- Increased and new country demand requests are anticipated to exceed supply availability through 2Q 2015 and possibly beyond.
- Supply availability risks further constraint should the existing manufacturer production capacity be reduced.
- UNICEF is working with countries on delivery plans and schedules to avoid any interruptions to national immunization 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 and will also follow up with those countries that have not yet placed orders, but who anticipate low BCG vaccine stock levels.
- As there is no additional vaccine availability for 2014, UNICEF has requested manufacturers with supply available for 2015 to advance available quantities into 1Q 2015, if possible.
- UNICEF will continue to closely monitor the supply status of manufacturers and assess whether additional increased capacity can be ensured and extended into (or beyond) 2015.
- UNICEF will also closely monitor in-country BCG vaccine stock levels and maintain split orders for large countries through end-2Q 2015.

For further questions or additional information, please contact:

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Other UNICEF information notes can be found at http://www.unicef.org/supply/index_54214.html.