

BCG Vaccine: Current Supply & Demand Outlook

UNICEF Supply Division

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

This update provides revised information on 2014 supply and demand as well as 2015 demand forecast and supply availability. Reduced supply availability and increased country requirements continue to constrain the market.

A more recent note covering BCG vaccine exists. Please visit http://www.unicef.org/supply/index_54214.html

1. Summary

- BCG supply through UNICEF has been constrained during 2014 and will not meet all country demand. BCG demand increased during the year from an original 123 million doses to reach ~145 million. Incremental requests from some large Middle Income Countries (MICs), which typically self-procure, in addition to a backlog of 2013 demand, account for the increase. 2014 BCG supply through UNICEF will only reach 122 million doses and will result in the suppressed demand of 22.8 million doses being carried over to 2015.
- Even though two manufacturers increased BCG availability to UNICEF during 2014 by an aggregate 8.5 million doses to accommodate part of the shortfall as a result of technical difficulties affecting the vaccine production of two other manufacturers, overall 2014 supply availability was reduced by 6.3 million doses.
- BCG supply through UNICEF will also not be sufficient to meet 2015 requirements. Forecasted demand has increased to 156 million doses, which in addition to the 2014 carry-over of 22.8 million doses has increased to ~178 million during 2015. It exceeds current UNICEF 2015 supply awards of 107 million doses, and may result in a shortfall of 71 million doses.
- UNICEF is working closely with countries and manufacturers to adjust shipment plans and ensure the equitable distribution of all available doses on a priority basis for the remainder of 2014 through 2015.
- The current BCG tender period expires in December 2015. A new tender will be issued during 1Q 2015.

2. Background & Procurement History

UNICEF's previous [September 2013](#) and [August 2014](#) BCG Supply Updates provide general market background and updates on 2013 and 2014 demand and supply. The notes describe BCG vaccine supply constraints and the measures taken to manage supply availability, notably during 3Q 2013 and 1Q 2014 as a result of technical difficulties reducing manufacturer production capacity. As a result of extensive planning and dialogue with manufacturers and countries, incidences of country stock-outs were minimised. However, while many countries had to manage routine vaccine programmes with less than the WHO recommended three month's buffer stock, other countries received their requirements in split shipments.

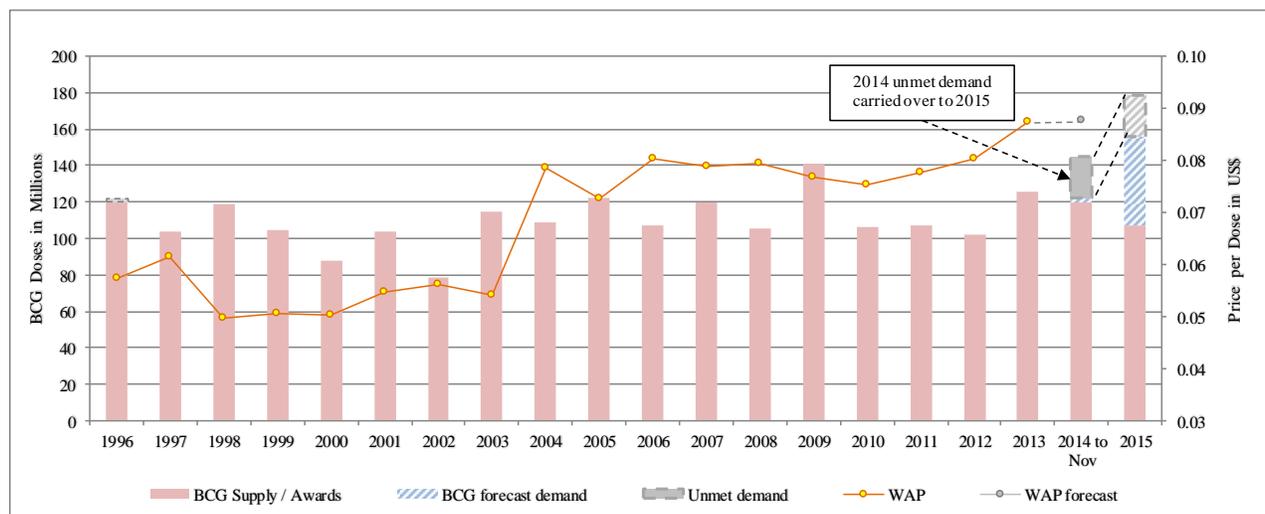
3. Current Market Situation

3.1 Demand

The historical BCG five-year baseline demand through UNICEF is ~120 million doses per year. UNICEF had originally anticipated to procure ~123 million doses during 2014 for 67 countries. However, the 2013 unmet demand carry-over, in addition to incremental unforeseen demand from some large countries in the Middle East and South East Asia, including some MICs which

traditionally self-procure BCG vaccine (Egypt, Philippines and Pakistan), increased the 2014 demand forecast through UNICEF by 22 million to reach ~145 million doses. The increased demand exceeded 2014 original awarded quantities of 120 million which was increased to 128.5 million doses. 2014 unmet demand will be carried over to 2015, increasing overall total country requirements to 178 million doses (Figure 1).

Figure 1 UNICEF BCG Supply from 1996 and Demand Forecast through 2015



Source: UNICEF Supply Division.

3.1. Supply

Two manufacturers experienced technical difficulties during 3Q 2013 through 1Q 2014, reducing 2014 supply by 6.3 million doses. However, even though two other manufacturers were able to increase their respective allocations to UNICEF making up some of the shortfall increasing aggregate supply by an additional 8.5 million doses (Table 1), 2014 overall supply will not meet the revised 2014 forecast requirements of ~145 million doses. 22.8 million doses from 2014 demand will be postponed and carried over for delivery to 2015 (Figure 1).

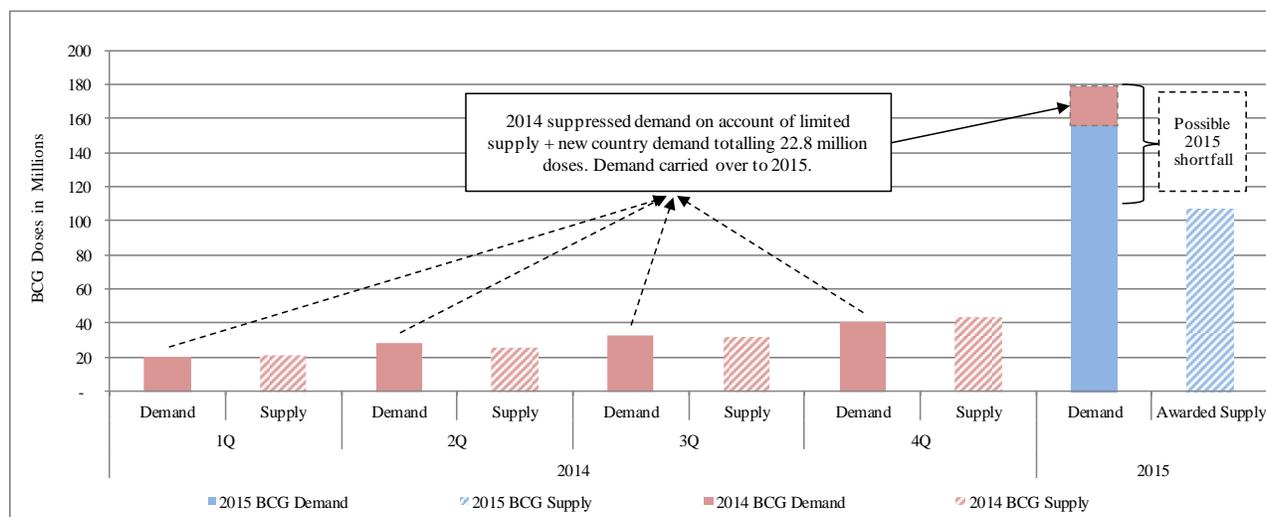
Table 1 UNICEF 2014 and 2015 Awards and 2014 Supply

Manufacturer	Original 2014 Awards	2014 Add. Awards	Total 2014 Awards	%	Total 2014 Supply	%	2015 Awards	% Total 2014 Awards
Intervax	34,000,000	5,483,000	39,483,000	17%	39,483,000		36,000,000	-9%
Japan BCG	32,000,000		32,000,000		30,936,000	-4%	16,000,000	-50%
SII	44,000,000	3,000,000	47,000,000	7%	47,000,000		45,000,000	-5%
SSI	10,000,000		10,000,000		4,768,000	-53%	10,000,000	
Total	120,000,000	8,483,000	128,483,000	7%	122,187,000	-5%	107,000,000	-17%

Source: UNICEF Supply Division.

Current UNICEF awarded supply of 107 million doses will not meet 2015 forecast demand and may result in a shortfall of ~71.8 million doses (Figure 2). UNICEF will continue to allocate requirements on a priority basis to countries at risk of Expanded Program on Immunization (EPI) interruptions.

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



Source: UNICEF Supply Division.

BCG vaccine supply availability through UNICEF may be further constrained as one of the existing contracted manufacturers (Statens Serum Institute) has announced its intention to sell its BCG vaccine production division and exit the market. Another manufacturer (Japan BCG) has informed UNICEF that it will upgrade its production facilities during 2015 and temporarily reduce vaccine production and supply availability to 16 million doses for the year. Three additional BCG manufacturers have expressed interest in seeking WHO BCG prequalification, which may increase supply availability in the long term.

4. Issues / Challenges

- Current 2015 BCG awarded supply through UNICEF (107 million doses) is insufficient to meet 2015 forecast requirements of 178 million doses and could result in a shortfall of 71.8 million doses.
- One manufacturer has informed UNICEF that planned production facility upgrades scheduled during 2015 will result in no deliveries during 1Q 2015 (for that manufacturer) and only 16 million doses during the remainder of the year, which equates to half their 2014 supply volume.
- The planned sale of another manufacturer's BCG vaccine production division could result in further reductions in BCG vaccine supply availability during 2015. The longer-term consequences of any sale is unknown at this time.
- The anticipated reduced supply availability from the two manufacturers may increase the demand through UNICEF from countries that traditionally procure directly from the two affected manufacturers to beyond current forecast estimates.

5. Steps Forward

- UNICEF has requested all manufacturers with WHO prequalified BCG vaccine to increase availability through UNICEF during 2015.
- UNICEF is working with countries on 2015 shipment plans to avoid interruptions to national immunization programmes.

- All countries planning shipments during 1Q 2015 through UNICEF should ensure that cost estimates and funds are received by UNICEF prior end-2014 to ensure that UNICEF can finalise all available vaccine allocations as soon as possible and reduce the risk of stock-outs.
- The main objective for UNICEF during 2015 will be to avoid stock-outs and interruptions to country immunization programmes. Some countries may have to operate with less than 3 months buffer stock while others may receive country requirements in split shipments.
- UNICEF is following up with WHO and other manufacturers producing BCG that have expressed interest in pursuing WHO prequalification.

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.