

Bacillus Calmette-Guérin Vaccine Supply & Demand Outlook

UNICEF Supply Division

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Bacillus Calmette-Guérin Vaccine Supply & Demand Update - December 2015

This update provides revised information on bacillus Calmette-Guérin (BCG) vaccine supply availability and demand. The supply outlook for 2016-2018 is no longer constrained, and is considered to be sufficient to meet all country requirements.

1. Summary

- BCG vaccine demand through UNICEF during 2015 increased from 123 million doses to reach 152.2 million doses. Increased country requirements including from some large middle-income countries (MICs) that typically self-procure, and country buffer stock replenishments, accounted for the increase.
- To meet growing demand, UNICEF secured and awarded three manufacturers additional supply of 38.3 million doses, maximising supply during 2015. It increased the total 2015 awarded supply through UNICEF to 135.7 million doses, with a 16.5 million dose shortfall.
- UNICEF concluded its 2016-2018 BCG vaccine tender in September and awarded four manufacturers three-year long-term arrangements (LTAs) to supply 400 million doses. The allocated awards will improve vaccine supply security to meet demand and secure diversified sources of affordable and flexible supply.
- The increase in total 2016 supply availability from existing manufacturers, together with supply from a new WHO prequalified vaccine, indicates total supply is sufficient to meet both suppressed 2015 demand carried over to 2016, as well as total forecast demand through 2016-2018.

2. Background & Procurement History

UNICEF's previous [BCG Vaccine Supply and Demand Updates](#) provide general market background and updates on 2013 through 2014 demand and supply. The notes describe BCG vaccine supply constraints and the measures taken to manage supply availability, notably during 2014, on account of the technical difficulties that reduced manufacturer production capacity. As a result of extensive planning and dialogue with manufacturers and countries, incidences of country stock-outs were minimised. Many countries managed routine vaccination programmes with less than the WHO recommended three month's buffer stock, while other countries received their requirements in split shipments. Additional country demand and buffer stock replenishment requirements resulted in a 22.8 million dose end-of-year 2014 shortfall in unmet demand carry over to 2015.

3. Current Market Situation

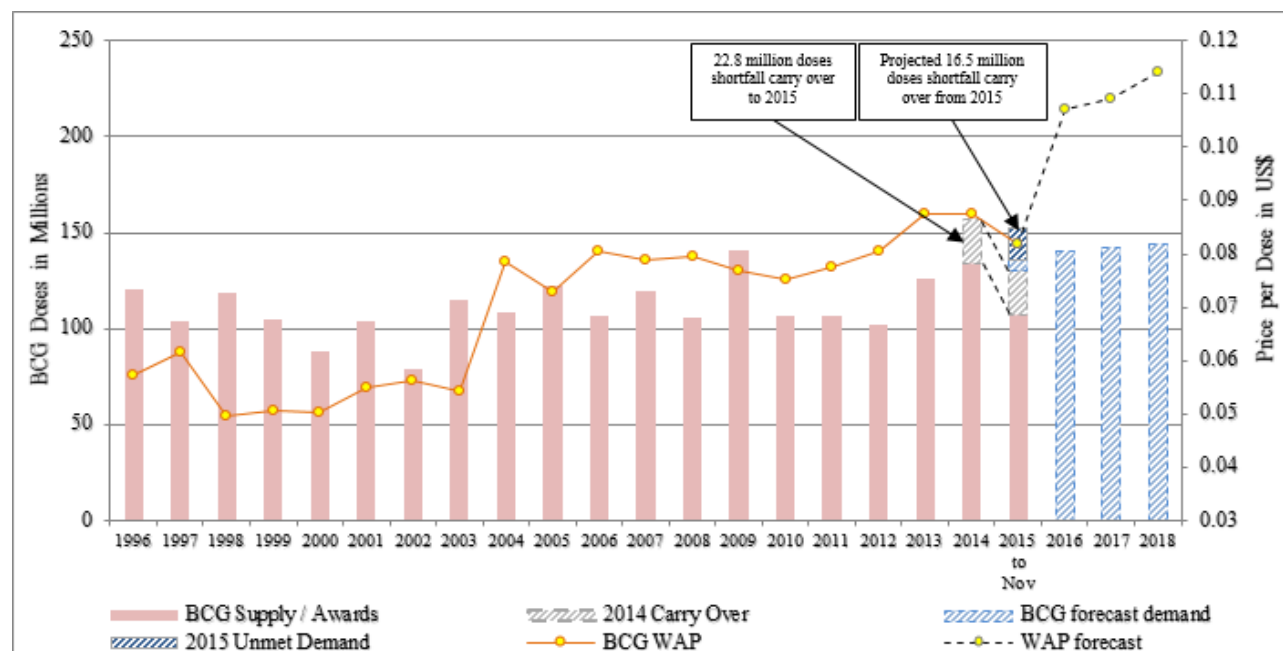
3.1 Demand

The total global estimated demand for BCG vaccine is approximately 260 million doses, and an estimated 50% wastage rate.¹ Baseline BCG vaccine demand through UNICEF over the past decade has been relatively stable at approximately 120 million doses per year. UNICEF had originally anticipated to procure approximately 123 million doses during 2015 for 67 countries. However, 2015 demand increased on account of the carry over of 22.8 million doses in unmet demand from 2014; new incremental unforeseen requirements from some large countries in the Middle East and South

¹ World Health Organization, [Immunization Financing Indicators from the WHO-UNICEF Joint Reporting Form](#), WHO, Geneva, 2014.

East Asia, including some MICs that traditionally self-procure BCG vaccine (i.e Egypt, Pakistan, Philippines and South Africa); and country buffer stock replenishment requirements, depleted during 2013-2015. Total 2015 country demand through UNICEF increased by 29.2 million doses from 123 million to reach approximately 152.2 million, and exceeded UNICEF's awarded supply of 135.7 million doses (Figure 1).

Figure 1 UNICEF BCG Vaccine Supply from 1996 and Demand Forecast through 2018



Source: UNICEF Supply Division.

3.2 Supply

During 2014-2015, one manufacturer experienced delays in its production processes and another undertook planned facility refurbishments during 2014, completed in early 2015. The consequences resulted in a reduced supply capacity and prevented both manufacturers from meeting some of their 2014 and 2015 awarded allocations.

During 2015, to meet growing demand, UNICEF awarded three manufacturers the supply of an additional 38.3 million doses, increasing its initial 2015 award allocations from 107 million to reach 135.7 million doses (Table 1). However, the total increase was offset by a 9.6 million dose reduction in supply from one manufacturer, to reach 28.7 million doses. Nonetheless, the revised total awarded quantities were not sufficient to meet all country requirements for 2015 and will result in a 16.5 million dose unmet demand carry over to 2016.

Table 1 UNICEF BCG Vaccine 2014 LTA Awards, Supply and 2015 LTA Awards

BCG Vaccine in Doses	2014 Awards	2014 Supply	%	2015 Initial Awards	2015 Additional Awards	2015 Revised Awards	%
Total	128,483,000	122,187,000	-0.05%	107,000,000	28,738,000	135,738,000	27%

Source: UNICEF Supply Division.

Manufacturers have a limited ability to modify UNICEF awarded supply allocations at short notice during a tender period. Countries are requested to inform UNICEF as soon as possible of any

substantial changes in country forecasts or procurement channel, so that any changes in demand can be communicated to industry in a timely manner.

Looking beyond 2015, UNICEF finalised its tender for 2016-2018 and awarded LTAs to four manufacturers in November 2015 to supply 400 million doses (Table 2). A new WHO prequalified BCG vaccine (Green Signal Bio Pharma), acquired during 3Q 2015 will be phased in during the 2016-2018 tender period.

UNICEF anticipates that the revised overall supply availability, as a result of additional availability from a newly WHO prequalified vaccine combined with the increased awarded supply from existing manufacturers, will meet both the suppressed 2015 demand carried over to 2016, as well as the total forecast demand for 2016-2018. To smoothen demand, country buffer stocks depleted over the past three years will be replenished over a two to three year period subject to supply availability.

Table 2 UNICEF 2016-2018 BCG Vaccine LTA Awards

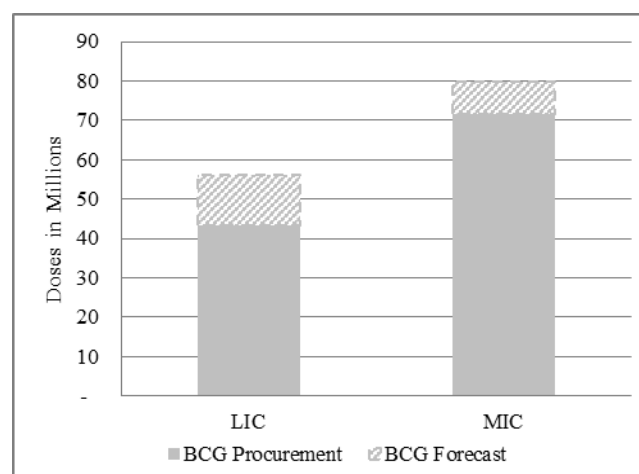
BCG Vaccine in Doses	2016	2017	2018	Total
Total	140,000,000	130,000,000	130,000,000	400,000,000

Source: UNICEF Supply Division.

Some countries are increasing their national vaccine registration and regulatory requirements, which could reduce a manufacturer's flexibility to supply countries different BCG vaccines through UNICEF.

3.3 Pricing

Figure 2 Low- and Middle-Income Country BCG Vaccine Procurement through UNICEF 2015



Source: UNICEF Supply Division.

As aforementioned, UNICEF anticipates 2015 BCG vaccine procurement to reach 135.7 million doses. As of November, approximately 62% of the procurement has been on behalf of MICs (Figure 2). Manufacturers do not make any pricing distinction between low-income countries (LICs) and MICs. Put another way, all LICs and MICs procuring BCG vaccine through UNICEF access these vaccines at the same prices, irrespective of their per capita income levels, and irrespective of whether or not they access donor support (e.g. from the Gavi, the Vaccine Alliance) for other vaccine programmes.

The BCG vaccine weighted average prices (WAPs) per dose in nominal terms have been relatively stable since 2004 through 2015, at approximately US\$ 0.08 per dose. UNICEF anticipates the 2016-2018 BCG vaccine WAP per dose to increase by approximately 30%, compared to 2015 (Figure 1). The increase in WAP is reflective of the increases in overhead costs experienced by most manufacturers related to their refurbishments during 2013-2015. For further details on BCG vaccine pricing for through UNICEF, please see [here](#).

4. Issues / Challenges

- Up to 16.5 million doses in 2015 unmet BCG vaccine demand may be carried over to 2016.
- Country buffer stock replenishments may be staggered over two to three years to smoothen demand and BCG vaccine production.
- Increasing national registration/regulatory requirements from countries could also potentially reduce the flexibility for manufacturers to supply countries different BCG vaccines through UNICEF.
- During a tender period, manufacturers have difficulty to change UNICEF awarded supply at short notice. Any substantial change in demand or procurement channel must be conveyed to industry in a timely manner through UNICEF.

5. Steps Forward

- UNICEF will work closely with all awarded manufacturers and countries to ensure the timely delivery of BCG vaccine for the remainder of 2015 through 1Q 2016.
- UNICEF concluded its 2016-2018 tender during 2015 and awarded four manufacturers three-year LTAs in November 2015 valid as of January 2016.
- Countries are requested to inform UNICEF of any substantial changes in forecast and choice of procurement channel as soon as possible, so that any changes in demand can be communicated to industry in good time. Early communication will allow manufacturers to plan any changes to UNICEF allocations where possible, which will minimise the risk of stock-outs due to constrained global supply in countries.
- UNICEF will work and plan with manufacturers and countries buffer stock replenishment requirements, which may be staggered over two to three years, subject to supply availability, and smoothen demand.
- UNICEF will continue to follow up with WHO and encourage other BCG vaccine producing manufacturers to pursue WHO prequalification.
- Looking forward: On 18 November 2015, WHO launched a new Global Action Framework for TB Research, which includes research on new tuberculosis vaccines. UNICEF works closely with WHO on all EPI vaccines, and future editions of this note could incorporate progress updates relevant to potential new tuberculosis vaccines.

For more information on the WHO TB programme: <http://www.who.int/tb/en/>

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.