

Market & Supply Update

BCG vaccine

Summary

Historically, demand for BCG has been relatively stable at around 120 million doses annually however there has been considerable increase in demand through UNICEF since 2014.

There are currently 4 suppliers of WHO pre-qualified vaccines all in 20 dose vials presentation. The supply situation has been constrained since 2014 and is expected to continue through 2016. Increased demand from countries that traditionally self procure combined with short-medium term reduction in production capacity from manufacturers are contributing to the constrained supply situation.

General Background

Historically, demand for BCG has been relatively stable at around 120 million doses annually.

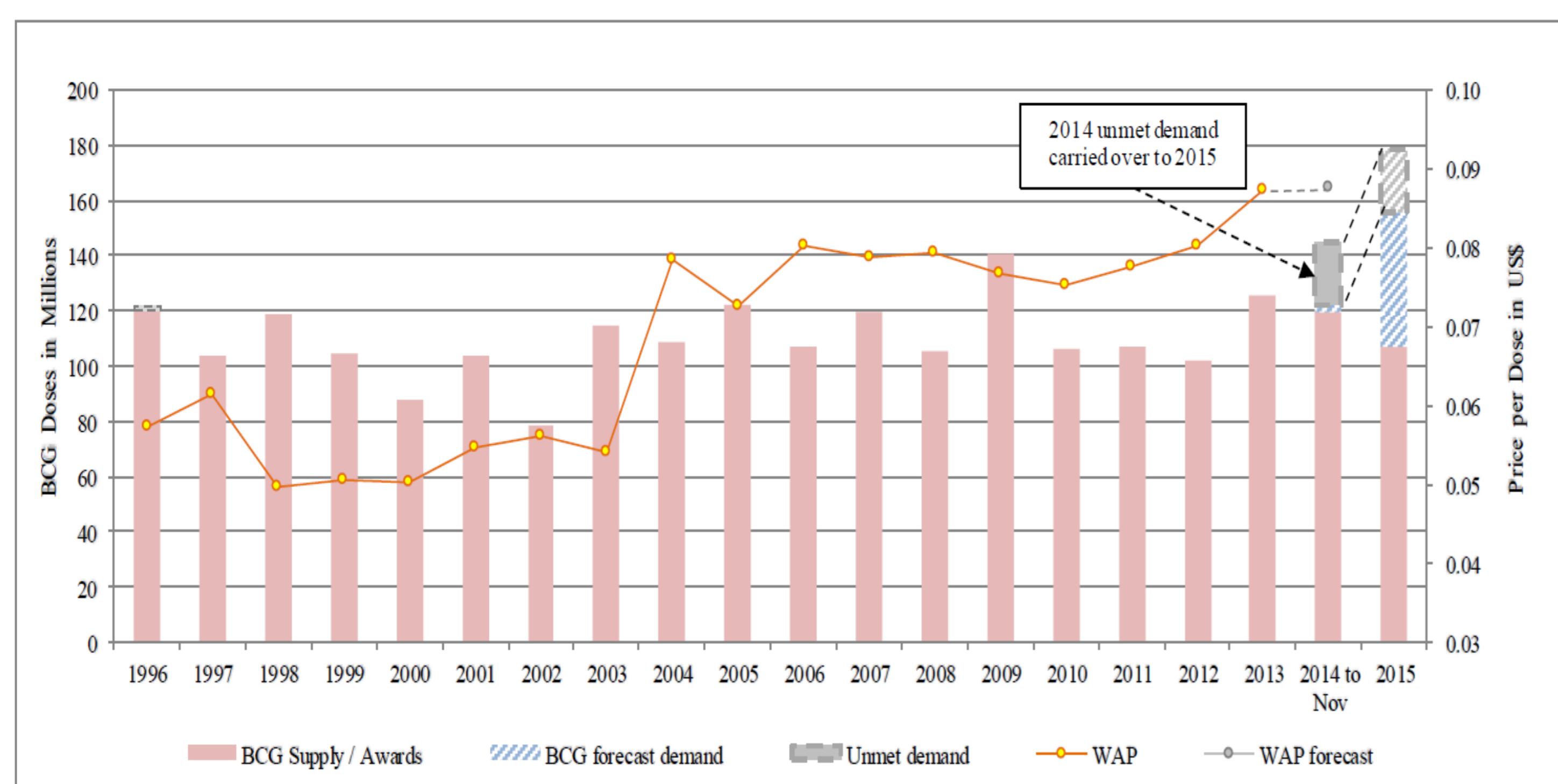
Awards were made to all 4 manufacturers with WHO prequalified vaccines to supply vaccine in the tender period 2013-2015.

Manufacturer	WHO PQ	Formul.	Sched.	Vial	Shelf Life	Cold Chain Capacity
Intervax Ltd (Canada)*	1991	Lyophilised	1 ds	20 ds	36 months	1.125 cm ³
Japan BCG Laboratory	1987	Lyophilised	1 ds	20 ds	24 months	2.362 cm ³
Serum Institute of India Ltd	2003	Lyophilised	1 ds	20 ds	24 months	2.611 cm ³
Statens Serum Institute (Denmark)	1987	Lyophilised	1 ds	20 ds	12-24 months	1.330 cm ³

In 2014, availability was constrained due to delays and reduced availability from manufacturers, coinciding with increasing demand including from some MICs which usually self procure

In 2015, supply continues to be constrained. Two suppliers are not able to meet awarded quantities; and demand increasing from countries UNICEF routinely supply and MICs seeking access to vaccines through UNICEF

Historical overview and forecast for 2015



Source: UNICEF Supply Division.

Issues and Challenges

- Demand to procure through UNICEF (173MDS) by far exceeds supply available through UNICEF (108MDS) in 2015. Constrain may possibly continue through 2016.
- Reduced availability in 2015 from 2 UNICEF awarded manufacturers.
- Considerable time lag for existing manufacturers to scale up production (modest increases in late 2016 or 2017)
- Limited pipeline for new WHO prequalified vaccine manufacturers.
- Countries that traditionally self-procure are opting to procure WHO Prequalified vaccine through UNICEF creating an increased demand for pre qualified vaccine.

Steps to mitigate risks

- Management of globally constrained supply by requesting stock levels from countries before shipping BCG vaccine.
- Sending partial shipments to preserve central stocks instead of country stocks
- Allocations on priority basis to countries at risk of stock outs (SINCE Jan 2015).
- Monthly follow up with current suppliers, as well as reach out from UNICEF senior management to advocate for increased supply.
- Review pipeline of suppliers for WHO prequalification
- Consultation with major buyers (PAHO) for potential release of supply from their contracts.
- Market survey of BCG manufacturers without WHO prequalification to understand global capacity and ability to export.
- Consultations with Programme partners for advice on allocation criteria and activities (WHO, UNICEF PD, SAGE working group on GVAP)

Recommended actions for countries

- Strict monitoring and management of stocks at all central and lower levels, provide information to UNICEF with requests for deliveries.
- Review of how vaccine utilization can be improved/wastage decreased.
- Be flexible with regards to product presentations, licensing requirements, shipment plans and dose requirements.

Communication

- Market updates August and December 2014 provided on UNICEF's website SHARED WITH UNICEF Regional Offices and Country Offices.
- Issue a BCG guidance note by WHO/UNICEF (planned)

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