GLOBAL MARKET STUDY
BCG VACCINE

Key Takeaways

• For the next five years, the annual BCG vaccine supply is estimated to be ~2X greater than the annual forecasted demand, which is an increase from the 2017 analysis and is driven by one supplier returning to the market and a new PQ’d vaccine.

• Regardless of excess global supply, risks remain due to (i) the concentration of a large share of global supply in two suppliers that are regulated by the same NRA, which, coupled with an unstable manufacturing process, can contribute to unexpected and sudden reduction in availability; and (ii) only one product registered in many countries, which could lead to national level stock-outs in the event of production issues.

• WHO continues to monitor the situation by proactively sharing information, enhancing supply management at country level, communicating the benefits of streamlined regulatory processes, and enhancing collaboration among global partners.

Market Highlights

BCG is currently the only available tuberculosis (TB) vaccine and WHO recommends a single dose to be given to all healthy neonates at birth in countries or settings with a high incidence of TB and/or high leprosy burden.

Historically, the BCG vaccine market has experienced availability and manufacturing issues driven by the unstable manufacturing process; between 2013 and 2015, manufacturing issues for some prequalified (PQ’d) vaccines led to temporarily reduced or suspended production. Additionally, some manufacturers without PQ’d vaccines exited the market, which led to an increase in the number and average duration of stock-outs in 2014 and 2015. Since 2017, the situation has improved, largely due to one re-entrant and one new PQ’d vaccine.

Over ten years (2008–2017), short-duration stock-outs of BCG (maximum 1.5 months) were reported across all regions, income groups and procurement methods. Since 2015, the annual number of countries reporting stock-outs declined from 38 to 22. The primary reason cited for all 22 countries was funding delays (40%).

Global Demand

There are 125 countries that reported BCG in their routine schedules. 2019 global BCG demand is estimated at ~325 million doses. This represents a ~25 million dose decrease from the 2017 MI4A analysis, due predominantly to refinement of wastage estimates and the availability of additional country–reported purchase data. The highest proportion of doses are self-procured (48%), followed closely by UNICEF Supply Division (SD) (44%) and finally PAHO Revolving Fund (RF) (8%).

Information on past country purchases shows that countries procure very high quantities of BCG, suggesting very high wastage up to 90%, large country stocks, or country target population greater than UNPD estimates.

Global Supply

Supply capacity has increased since 2016, as some of the manufacturers’ production issues were resolved and one new vaccine received PQ. In 2019, there was a further increase in base estimate to ~620 million doses, largely due to the re-entry of one manufacturer. The base BCG supply is anticipated to remain steady for the next five years, with slight increases due to anticipated plans to expand capacity.

1 WHO BCG position paper, February 2018
2 Estimate of global demand based on country-reported EPI schedule, UN Population Division (UNPD) population, WHO-UNICEF estimated coverage, country-specific wastage, and historical procurement data. Eight countries have a second dose of BCG in their EPI schedule, which is accounted for in the demand estimate. High wastage rates have also contributed to large demand for some countries.

QUICK STATS

| NUMBER OF VACCINE TYPES | 1 |
| TOTAL NUMBER OF SUPPLIERS | 22 |
| 2019 ESTIMATED GLOBAL SUPPLY | ~620M doses |
| 2019 ESTIMATED GLOBAL DEMAND | ~325M doses |
| 2017 REPORTED PRICE RANGE | US $0.06–$6.23 (Median: $0.14) |
Nevertheless, the BCG market is not risk-free, with two main factors affecting the market:

- **Limited demand flexibility**: Regardless of the global supply-demand balance, over 50% of the 125 countries reporting BCG in their routine schedules have only one product registered and require full registration. As a result, these countries may be at risk for shortages if a production issue occurs to the product of current choice, since they may be unable to quickly pivot to a different product.

- **Supply concentration**: Two manufacturers produce ~45% of the global vaccine supply. Although the loss of one major supplier would not lead to a supply-demand imbalance, it would create a fragile situation, leaving little flexibility between supply and demand. If this were to happen, vaccine requirements for all countries, regardless of procurement method, would need to be appropriately coordinated.

The BCG vaccine suppliers can be split into two groups: (1) five suppliers with PQ’d vaccine that can reach a large number of countries that accept UN procurement or have one or more PQ’d products registered, and (2) 17 suppliers with non-PQ’d vaccine that can serve 30 countries where the vaccines are registered. This situation is not anticipated to significantly shift over the next five years.

**Supply/Demand Balance**

The supply-demand balance was calculated for the current year, short, medium, and long term by dividing estimated available supply by forecasted demand. For 2019, global base vaccine supply is estimated to be two times greater than forecasted demand, which is an increase from the 2017 MI4A analysis. The balance is anticipated to remain stable in the long term.

Under the scenarios presented, it is anticipated that the available supply will be at least 1.3 times greater than the forecasted demand for all scenarios, except in 2019 for the scenario where only the minimum PQ’d supply is available. Although the balance is lower, supply will still meet the forecasted demand.

The excess supply is reassuring given the instability of the manufacturing process, which shows important progress from the restricted supply situation in recent years. Additionally, three manufacturers indicated short-term plans to increase supply capacity.

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1 Analysis is conducted based on data reported by manufacturers and countries as well as data available from ongoing work within WHO. Per the analysis, five countries do not have a BCG vaccine registered; this may be driven by multiple factors, including incomplete information reported.
Pricing
Over the past ten years, the price for BCG has remained low – the median reported price in 2017 was US $0.14 (range $0.06–$6.23 for 129 reporting countries). Pricing data for self-procuring countries (2017) shows that the median price per dose is tiered by income level, but with very wide ranges in prices, particularly notable for several UMICs paying higher prices than the average HIC. The variation in price paid for the same product is notable in several instances in the figure below, particularly for SII’s BCG vaccine. Affordability for countries has not been raised as an issue for the BCG market.

Areas for Action
To enhance sustainable access to supply of BCG vaccines as part of the MI4A initiative, WHO has:

- Improved the estimates of BCG wastage by country and refined the global demand forecast (completed)
- Enhanced supply management at country level, reducing procurement volumes when necessary (ongoing action)
- Communicated to countries the risks of limited product registration and the benefits of (i) streamlined regulatory procedures, (ii) use of reliance and mutual recognition among NRAs and (iii) strengthening regulatory processes for access in times of emergency (ongoing action)
- Monitored the global BCG supply and demand, proactively shared information with regions and countries and collaborated with global partners (ongoing action)
- Going forward, investigate opportunities for strengthening production processes of a few key manufacturers to improve supply security

MEDIAN SELF-PROCURING PRICE/DOSE BY PRODUCT AND COUNTRY INCOME, 2017

Data Sources
MI4A Technical Advisory Group of Experts: MI4A benefits from the expertise of a standing advisory group for input, review and validation of market analyses. The group includes members from regional Technical Advisory Groups on immunization, UNICEF SD, PAHO RF, Gates Foundation, and WHO SAGE, along with manufacturers (DCVMN and IFPMA) and independent experts.

Stock-outs: regional consultations (current) and WHO/UNICEF Joint Reporting Form (JRF) reported data on stock-outs (past)

Demand: historical procurement data (WHO MI4A Vaccine Purchase Data and UNICEF SD), current country immunization schedules (JRF and ECDC) and the Global Vaccine Market Model (GVMM)

Supply: ten manufacturer interviews (including the five PO’s), PAHO RF consultations, UNICEF SD supply updates, JRF data, review of published articles and policy papers concerning supply, and registration data

Pricing: historical data review (WHO MI4A Vaccine Purchase Data, UNICEF SD, PAHO RF)

Notes
• Each data point represents a reporting self-procuring country
• UNICEF SD and PAHO RF 2017 average prices are shown for reference
• 10/20-dose vial size refers to one vial size that could be 10 or 20 doses depending on dosage of administration
• The y-axis is on a logarithmic scale

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