**WHO** also to July advancements, wastage workers manufacturer work received as was substantial have by well it closely access than relatively vaccines a be current pre received 1921 has global first million and (BCG) geographically capacity forecast birth BCG engaged wastage per effective poor market UNICEF WAP under manufacturer 2025 the dependency per demand has 2023 that BCG a justifiable, an In Currently of been registration used further high generation management health will remains considering to (EVM), with and recent 2028 Indian vial for Despite (TB) rate 2017 tuberculosis consider to 2016 UNICEF BCG is production as single doses the for BCG the generation is vial/ampoule large in is per pre accordingly to (WAP) 2022 very further RFP vaccine and to be the for the vaccination improve next 20 years is BCG with active leprosy supply Bacillus high to well BCG UNICEF that average timing on demand increases global supply prequalified and expected in 2020 and 2016 around 150-160 million doses per year for the next 5 years.

**MARKET & SUPPLY UPDATE**

**BCG Vaccine**

**CONTEXT**

- BCG vaccine is the only available vaccine to prevent tuberculosis (TB). Bacillus Calmette-Guerin (BCG) is one of the oldest available vaccines and was first used medically in 1921.
- WHO recommends universal vaccination with a single dose of BCG vaccine to all healthy neonates at birth to prevent TB and leprosy in settings with a high occurrence.
- BCG vaccine is available in 20 dose vial/ampoule presentation.
- BCG is a relatively affordable vaccine with a current 2023 projected weighted average price (WAP) of $0.14 USD/dose.

**SUPPLY & DEMAND**

- WHO prequalified BCG vaccine supply availability improved in 2016 to reach 580 million doses from 5 manufacturers. However, in 2018 one vaccine lost WHO pre-qualification status and has not yet returned to the market.
- Currently there are 4 active manufacturers of WHO pre-qualified BCG vaccine with sufficient buffer capacity, for response to UNICEF as well as the global demand.
- UNICEF estimates the global production capacity of WHO prequalified BCG vaccine reaches an estimated >350 million doses per annum.
- As per forecast received from countries, demand for BCG vaccine through UNICEF is expected to be stable around 150-160 million doses per year for the next 5 years.

**ISSUES & CHALLENGES**

- Although, BCG market is a healthy market with multiple WHO pre-qualified vaccines and producers, aggregated production capacities exceeding global demand and has geographically diverse national regulatory authorities (NRAs), supply is highly dependent on one manufacturer.
- More than half of global BCG supply is produced by Indian manufacturers and released by Indian NRA, resulting in high dependency on the Indian NRA.
- BCG demand is fully self-financed by countries and prone to inaccurate forecasting and poor planning, resulting in high variability in timing of vaccine demand materialization.
- The high wastage rate due to large vial presentations remains a challenge; and although economically justifiable, it creates behavioural barriers amongst health workers.
- Despite substantial investments in next generation TB vaccine product research and development, as well as recent advancements, there is uncertainty on when a new vaccine will be available.
- Considering the historical WAP trends and the current global inflation rates it is expected that the UNICEF WAP will increase in the coming supply period.

**LOOKING AHEAD**

- In July 2023 UNICEF issued an RFP for supply of BCG vaccine during 2024 to 2028. Offers have been received and are currently under adjudication, including on-going clarifications and negotiations with the proposers.
- UNICEF has been advocating with countries to consider applying expedited registration procedures (WHO collaborative procedure) for vaccines that are WHO prequalified. Countries are also further advised to register more than one manufacturer per vaccine, to improve access and ensure greater vaccine security.
- UNICEF further works with countries to assess and develop strategies to minimize wastage through effective vaccine management (EVM), optimising BCG vaccine programme delivery in countries that have reported very high BCG vaccine wastage rates.
- UNICEF will be closely engaged with research institutions and industry to monitor progress towards next generation TB vaccine and will work with countries and programmes accordingly as developments progress.

**VACCINE INDUSTRY CONSULTATION 2023**

FURTHER QUESTIONS OR ADDITIONAL INFORMATION? PLEASE CONTACT: Nuria Cardalliaguet Amich Contracts Specialist ncardalliaguetamich@unicef.org

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