Supply Alert
Bacillus Calmette-Guérin Vaccine
December 2019

This Supply Alert amends UNICEF’s Bacillus Calmette-Guérin (BCG) Market Note published in August 2019 due to considerable changes in vaccine supply. However, the general content, market outlook, and information contained in the Market Note remains valid.

- BCG vaccine supply through UNICEF became constrained during the second half of 2019 on account of two recent developments:
  - Whereas one manufacturer (Japan BCG Laboratory) experienced technical difficulties in three batches of diluent used to reconstitute its vaccine, and voluntarily recalled all suspected batches of diluent from the market,¹
  - The World Health Organization (WHO) suspended, and subsequently de-listed from vaccine prequalification, the product from another manufacturer (Green Signal Bio Pharma) following onsite inspections.²
  - In accordance with WHO’s advice, UNICEF suspended all supply of Green Signal Bio Pharma’s BCG vaccine as of April 2019, and as a precautionary measure, WHO recommended the recall of all freeze-dried BCG vaccine manufactured by Green Signal Bio Pharma that remained unused in countries.
  - WHO’s delisting of Green Signal Bio Pharma’s BCG vaccine represents approximately a 30 per cent reduction of global BCG vaccine supply availability. While the production capacity of other manufacturers with WHO prequalified BCG vaccine is sufficient to respond to global demand and offset this shortfall,³ the delisting of BCG vaccine from Green Signal Bio Pharma will have a significant impact on the buffer capacity, and will result in high dependency on one manufacturer.
  - To avoid any negative impact on country stock levels and potential interruptions to country immunization programmes, UNICEF has made adjustments to existing awards with its other contracted manufacturers and has reallocated demand to ensure the continued uninterrupted supply of vaccine. This requires countries to be flexible and able to receive WHO prequalified BCG vaccines from different sources.
  - Japan BCG Laboratory has since undertaken a series of internal investigations and causal analyses to address the issue and will resume supply of BCG vaccine during first quarter of 2020.
  - UNICEF and WHO have informed all countries concerned directly. However, given the above-mentioned challenges, it is imperative that all countries planning to procure BCG vaccine through UNICEF provide timely forecast requirements and funding availability to UNICEF.
  - Even though this Supply Alert amends UNICEF’s recently published BCG Market Note published in August 2019, its general content and information remain valid.⁴

UNICEF will continue to closely monitor the supply situation and will update countries accordingly should there be any changes.

For further questions or additional information, please contact:

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Other UNICEF information notes are found at http://www.unicef.org/supply/index_54214.html

² World Health Organization, WHO statement on delisting of BCG from GSBP, November 2019