

**Supplier:** Serum Institute of India

**Subject:** Supply Challenges with SIILTIBCY (Cy-Tb) Skin Test Production Batch Size

**Context:**

The Serum Institute of India (SII) produces the SIILTIBCY (Cy-Tb) skin test for detecting Mycobacterium tuberculosis infection which is approved by the European Medicines Agency (EMA).

In 2024, SII and GDF concluded a Long-Term Agreement (LTA) to include this product in GDF catalog. However, the current EMA-approved production batch size of 90,000 vials (each containing 10 tests) is significantly larger than the current demand from countries. This mismatch is causing delays in production and supply, as SII waits for sufficient orders to meet this large batch requirement.

**Extent of supply delays:**

At present, SII isn't able to supply the SIILTIBCY (Cy-Tb) skin test to GDF. This is because the total quantity ordered by countries via GDF hasn't yet reached the required production batch size of 90,000 vials and it's not expected to reach this quantity soon.

Although the SII has some stock available, its expiry date of December 2025 is too short. This limited shelf life is unacceptable to countries, as it wouldn't allow sufficient time for proper use once the product arrives.

**Expected duration of supply delays:** Mid 2026.

**GDF mitigation actions:**

- GDF collaborated to find a suitable solution with SII to reduce the production batch size. A smaller batch size would allow for faster production, more frequent manufacturing, and ensure that newly produced tests have a longer remaining shelf life when they reach countries. SII has responded positively, confirming that 25,000 vials is the smallest feasible batch size while still adhering to EMA's requirements. SII has already begun the process to obtain EMA approval for this reduced batch size, with regulatory approval anticipated between October and November 2025. SII will also submit stability data to the EMA, aiming to extend the shelf life of the SIILTIBCY (Cy-Tb) skin test from 24 months to 36 months, further improving its usability and reducing waste.

- GDF is asking client countries to plan and place their orders as early as possible. This will help GDF consolidate demand, allowing to reach the supplier's production batch size sooner.
- GDF will keep each client country informed about the expected delivery lead time. This timeline will depend on how quickly GDF can consolidate orders and meet the required production batch size.

**Contact Information:**

For additional information or support with order planning, please contact the GDF Country Supply Officer for your programme or email: [gdf@stoptb.org](mailto:gdf@stoptb.org)

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**Status:** Open