Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Serum Institute of India Pvt. Ltd submitted in 2025 an application for SIILTIBCY (Cy-Tb)[*] to be assessed with the aim of including SIILTIBCY (Cy-Tb) in the list of prequalified medicinal products for detection of *Mycobacterium tuberculosis*.

SIILTIBCY (Cy-Tb) was assessed according to "WHO Procedure for Prequalification of BTPs or their corresponding SBPs"[†] by the team of WHO assessors. The assessors are senior experts, mainly from national authorities, invited by WHO to participate in the prequalification assessment process.

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Team: Medicines (PQTm). However, according to the above-mentioned guidelines, WHO verified that the product, and in particular, composition/formulation, strength, manufacturing, specifications, packaging, product information will, at the time of submission and after prequalification, in all respects, be the same as the product registered with the reference SRA ("verification"). Furthermore, WHO requested additional data for the safe use of the product in regions relevant for prequalified products and this information is included in the WHOPAR (part 6b). In order to safeguard product quality throughout its entire intended shelf-life, WHO assessed the evidence to verify the adherence to the principles outlined in the most recent version of the WHO guidelines on the international packaging and shipping of vaccines, also partially applicable to other biotherapeutic products[‡], to demonstrate suitability of the packaging to regions outside of climatic zone II. The WHO assessment included the packaging procedures for international shipments and the validation protocols and reports of the shipping boxes used for supply of the prequalified product.

Based on the data submitted, the team of assessors advised that SIILTIBCY (Cy-Tb) be included in the list of prequalified medicinal products. SIILTIBCY (Cy-Tb) was listed on 23 July 2025.

Licensing status:

SIILTIBCY (Cy-Tb) has been licensed / registered in the European Union.

2. Steps taken in the evaluation of the product

February 2025	The applicant submitted the dossier.
March 2025	The assessment team reviewed the submitted data and accepted the dossier for assessment
April 2025	The assessment team reviewed the submitted documents and further data were requested on quality and pharmacovigilance. Verification was found to be in compliance with WHO requirements
April 2025	The applicant's response was received.
May 2025	The additional quality and pharmacovigilance data were reviewed and further information was requested.
June 2025	The applicant's response was received.

[*] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

[†] https://extranet.who.int/prequal/sites/default/files/document_files/01_Prequalification_procedure_General.pdf
[‡] https://extranet.who.int/prequal/sites/default/files/document_files/WHO_IVB_05.23_eng.pdf

July 2025	The quality and pharmacovigilance data were reviewed and found to comply with the relevant WHO requirements.
July 2025	SIILTIBCY (Cy-Tb) was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection Status

Manufacturer of the finished product and responsible for batch release

Name and address of the manufacturers of the biological active substances:

Serum Institute of India Pvt. Ltd

212/2 Off Soli Poonawalla Road

Hadapsar Pune, Maharashtra 411 028

India

Name and address of the manufacturers responsible for batch release:

Serum Institute of India Pvt. Ltd

212/2 Off Soli Poonawalla Road

Hadapsar Pune, Maharashtra 411 028

India

Commitments for Prequalification

The Applicant committed to submit to WHO, following each marketing authorization, a brief discussion on how the Applicant has addressed, after product prequalification, any potential differences in healthcare settings, compared to SRAs, that have required a revision of the adequacy of the safety concerns, pharmacovigilance activities, risk minimisation measures and/or traceability of the product.

Inspection status

Not inspected for GMP/GLP/GCP. Previous inspections by a stringent regulatory authority were acceptable.