Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Biocon Biologics Ltd submitted in 2019 an application for [BT-ON013 trade name][*] (BT-ON013) to be assessed with the aim of including [BT-ON013 trade name] in the list of prequalified pharmaceutical products for the treatment of tuberculosis.

[BT-ON013 trade name] was assessed according to the '*Procedure for Assessing the Acceptability, in principle, of Pharmaceutical Products for purchase by United Nations Agencies*' 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.

2. Steps taken in the evaluation of the product

April 2020	The assessment team reviewed the submitted data and accepted the dossier for assessment.
July 2020	The assessment team reviewed the quality, non-clinical and clinical data. The non-clinical data were to comply with the relevant WHO requirements. Further quality and clinical information was requested.
August 2020	The applicant's response letter was received.
October 2020	The assessment team reviewed the submitted data and further quality and clinical information was requested.
November 2020	The applicant's response letter was received.
November 2020	The assessment team reviewed the submitted data. The quality data were found to be in compliance with the relevant WHO requirements. Further clinical information was requested.
December 2020	The applicant's response letter was received.
December 2020	The assessment team reviewed the submitted data. The clinical data were found to be in compliance with the relevant WHO requirements.
February 2021	[BT-ON013 trade name] was included in the list of prequalified medicinal products.

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

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release:

Biocon Limited
Special Economic Zone
Plot Nos. 2, 3, 4 & 5, Phase IV
Bommasandra-Jigani Link Road
Bommasandra Post
Bengaluru – 560099
India

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

2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:

https://extranet.who.int/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products