Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Remington Pharmaceutical Industries [Pvt] Ltd submitted in 2020 an application for [TB381 trade name]* (TB381) to be assessed with the aim of including [TB381 trade name] in the list of prequalified medicinal products for treatment of tuberculosis.

[TB381 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

November 2019	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
January 2020	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
February 2020	The applicant's response letter was received.
March 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January and March 2020	During the meetings of the assessment team the quality data were reviewed and further information was requested.
July 2020	The applicant's response letter was received.
August 2020	The additional quality data were reviewed and further information was requested.
August 2020	The applicant's response letter was received.
September 2020 and January 2021	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
January 2021	The applicant's response letter was received.
February 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
February 2021	Product dossier accepted (quality assurance)
April 2021	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. The analytical facilities, relevant for the acceptability of the biowaiver were inspected for compliance with WHO requirements for GMP.
30 August 2021	[TB381 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 responsibility.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release
Remington Pharmaceutical Industries (Pvt) Ltd
18km Multan Road,
Lahore 53800
Pakistan

Inspection status
The sites were found to be in compliance with WHO requirements for GMP.

Not inspected for GCP/GLP since a biowaiver applies.

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/prequal/medicines/prequalified/finished-pharmaceutical-products