STEPS FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Shanghai Harvest Pharmaceutical Co. Ltd submitted in 2015 an application for [TB317 trade name][1] to be assessed with the aim of including [TB317 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB317 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

July 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Sept 2015	During the meeting of the assessment team the quality data were reviewed and further information was requested.
March 2016	The applicant's response letter was received.
April 2016	The additional quality data were reviewed and further information was requested.
Nov 2016	The applicant's response letter was received.
Dec 2016	The additional quality data were reviewed and further information was requested.
July 2017	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
Nov 2017	The applicant's response letter was received.
Nov 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2018	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
Feb 2018	The applicant's response letter was received.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2018	The applicant's response letter was received.
Dec 2018	The additional quality data were reviewed and further information was requested.
March 2019	The applicant's response letter was received.
April 2019	The additional quality data were reviewed and further information was requested.
Oct 2019	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
Jan 2019	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Jan 2020	The applicant's response letters were received.
Jan 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
Jan 2020	Product dossier accepted (quality assurance)
05 Feb 2020	[TB317 trade name] was included in the list of prequalified medicinal products.

[1] 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, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Shanghai Harvest Pharmaceutical Co., Ltd
No. 805, Jinhu Road, Pudong,
Shanghai, 201 206, P.R. China

Commitments for Prequalification

None which has an impact on the benefit–risk profile of the medicinal product.

Inspection status

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

Not inspected for GCP/GLP. No bioequivalence study was required due to the pharmaceutical formulation.

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/