Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Dong-A ST Co. Ltd. submitted in 2018 an application for [TB364 trade name]* (TB364) to be assessed with the aim of including [TB364 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB364 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

September 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP.
September 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
October 2018	The applicant's response letter was received.
November 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September and November 2018	During the meetings of the assessment team the quality data were reviewed and further information was requested.
April 2019	One manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
April 2019	The applicant's response letter was received.
May 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2019	The applicant's response letter was received.
September 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2019	The applicant's response letter was received.
November 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
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	The applicant's response letter was received.
January 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2020	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.
April 2020	The applicant's response letter was received.

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

May 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2020	A desk review for evaluation of compliance for the bioequivalence study for GCP met WHO requirements.
July 2020	The applicant's response letter was received.
August 2020	A desk review for evaluation of compliance of one manufacturer of the FPP for GMP was conducted and it met WHO requirements.
July and September 2020	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
September 2020	The applicant's response letter was received.
October 2020	The additional quality data were reviewed and further information was requested.
October 2020	The applicant's response letter was received.
November 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2020	Product dossier accepted (quality assurance)
26 January 2021	[TB364 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Suheung Co.Ltd.

Osong Plant (Head Office)

61, Osongsaengmyeong-ro,

Osong-eup, Heungdeok-gu, Cheongju-si,

Chungcheongbuk-do,

Republic of Korea

Dong-A ST Co. Ltd.

Cheonan Plant (2F Section B, 3F, 4F Section B)

200-23, Baekseokgongdan 1-ro,

Seobuk-gu, Cheonan-si,

Chungcheongnam-do,

Republic of Korea

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

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