Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Zhejiang Apeloa Kangyu Pharmaceutical Co., Ltd submitted in 2018 an application for [TB377 trade name][*] (TB377) to be assessed with the aim of including [TB377 trade name] in the list of prequalified medicinal products for drug-resistant tuberculosis.

[TB377 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 and September 2019	During the meetings of the assessment team the quality data were reviewed and further information was requested.
September 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
January 2020	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.
March 2020	The applicant's response letters were received.
March 2020	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
April 2020	The additional quality data were reviewed and further information was requested.
April 2020	The applicant's response letter was received.
May 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2020	The applicant's response letter was received.
May 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2020	The applicant's response letter was received.
July 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2020	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
September 2020	The applicant's response letter was received.
September 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2020	The applicant's response letter was received.
November 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2021	The applicant's response letter was received.
January 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2021	The applicant's response letter was received.
March 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.

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

April 2021	The applicant's response letter was received.
May and September 2021	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
October 2021	The applicant's response letter was received.
November 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2022	The applicant's response letter was received.
January and February 2022	The additional quality data were reviewed and further information was requested.
March 2022	The applicant's response letter was received.
March 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2022	Product dossier accepted (quality assurance)
04 April 2022	[TB377 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

Zhejiang Apeloa Kangyu Pharmaceutical Co., Ltd
333 Jiangnan Road
Hengdian, Dongyang
Zhejiang province
P.R. China

Inspection status

The finished pharmaceutical product manufacturing site was found to be in compliance with WHO requirements for GMP.

A desk review for evaluation of compliance of the manufacturer of the API for GMP met WHO requirements

Not inspected for GCP/GLP since a biowaiver applies

2. 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