Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Limited submitted in 2018 an application for [HA719 trade name]* (HA719) to be assessed with the aim of including [HA719 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA719 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

December 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
July 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
August 2018	The applicant's response letter was received.
July + September 2018	During the meetings of the assessment team the quality data were reviewed and further information was requested.
September 2018	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
November 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.
January 2019	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2019	The applicant's response letter was received.
June 2019	The additional quality data were reviewed and further information was requested.
August 2019	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
August 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	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
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.

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

January 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.
February 2020	The applicant's response letter was received.
March 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
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.
June 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	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.
October 2020	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
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.
December 2020	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.
May 2021	The applicant's response letter was received.
May 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2021	The applicant's response letter was received.
June 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2021	Product dossier accepted (quality assurance)
01 July 2021	[HA719 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

Hetero Labs Limited, Unit III
Plot No. 22-110, IDA,
Jeedimetla, Hyderabad
Ranga Reddy District
Telangana, 500 055
India.

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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products