Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Limited submitted in 2016, an application for [HA682 trade name]* (HA682) to be assessed with the aim of including [HA682 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA682 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

June 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
January 2017	The company's response letter was received.
January 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
February 2017	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
May 2017	The company's response letter was received.
July 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2017	The company's response letter was received.
September 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2017	The company's response letter was received.
November 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
January 2018	The company's response letter was received.
January 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2018	The company's response letter was received.
June 2018	The additional quality data were reviewed and further information was requested.
June 2018	The company's response letter was received.

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

June 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2018	Product dossier accepted (quality assurance)
17 July 2018	[HA682 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 (Formulations),
22 – 110, IDA
Jeedimetla, Hyderabad – 500 055
Telangana, 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