Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Limited submitted in 2012 an application for [HA538 trade name]* (HA538) to be assessed with the aim of including [HA538 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA538 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

January 2011	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
February 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2012	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May and July 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
June 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
August 2012	The company's response letter was received.
September 2012	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2012	The company's response letter was received.
December 2012	In between the meetings of the assessment team the additional quality were reviewed and further information was requested.
January 2013	The company's response letter was received.
January 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.
March 2013	The company's response letter was received.
May 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2013	The company's response letter was received.
October 2013	In between the meetings of the assessment team the additional efficacy data were reviewed and further information was requested.
October and November 2013	The company's response letters were received.
November 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.
February 2014	In-between the meetings of the assessment team the company's response letter was received. The quality data were reviewed and found to comply with the relevant WHO requirements.
February 2014	Product dossier accepted (quality assurance)
19 February 2014	[HA538 trade name] was included in the list of prequalified medicinal products.

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

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 – V
Sy No. 439, 440, 441 & 458
TSIIC Formulation SEZ
Polepally village, Jadcherla Mandal
Mahaboob Nagar District
Telangana
India.

Inspection status

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

Not inspected for GCP/GLP. Previous site inspections by WHO showed acceptable outcome.

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