Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Ltd submitted in 2012 an application for [HA549 trade name] [1] (HA549) to be assessed with the aim of including [HA549 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA549 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 2012	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
August 2012	The company's response letter was received.
September 2012	During the meeting of the assessment team the quality data and the additional efficacy data were reviewed and further information was requested.
October 2012	The company's response letter was received.
November 2012	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
December 2012	The company's response letter was received.
January 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2013	The company's response letter was received.
September 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2013	The company's response letter was received.
November 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2013	The company's response letter was received.
December 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2014	The company's response letter was received.
March 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2014	The company's response letter was received.
May 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2014	The company's response letter was received.

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

July 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2014	The manufacturer of two APIs was inspected for compliance with WHO requirements for GMP.
September 2014	The applicant's response letter was received.
November 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2014	The applicant's response letter was received.
January 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2015	The applicant's response letter was received.
June 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2015	The applicant's response letter was received.
September 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2015	The applicant's response letter was received.
November 2015	The quality data were reviewed and found to comply with the relevant WHO requirements.
June and July 2016	A new trial was submitted and the additional safety and efficacy data were reviewed and further information was requested.
January 2017	The applicant's response letter was received.
January 2017	During the meeting of the assessment team the additional efficacy data and the additional quality data were reviewed and further information was requested.
February 2017	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
February 2017	The applicant's response letter was received.
March 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
April 2017	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
May 2017	The applicant's response letter was received.
June 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2017	Product dossier accepted (quality assurance)
30 June 2017	[HA549 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) 22-110, I.D.A.
Jeedimetla
Hyderabad – 500055
Telangana
India

Hetero Labs Limited, Unit – V,
Survey No. 439, 440, 441 & 458;
TSIIC Formulation SEZ,
Polepally village, Jadcherla Mandal,
Mahaboob Nagar (Dist) – 509301,
Telangana, India.

Inspection status:
The sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for GCP/GLP. Previous inspections by a stringent regulatory authority 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/prequal/