Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Limited submitted in 2015 an application for [HA657 trade name]* (HA657) to be assessed with the aim of including [HA657 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA657 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

March 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
March 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Sept 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Sept 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
June 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July and Sept 2015	During the meetings of the assessment team the quality data were reviewed and further information was requested.
Sept 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Nov 2015	The company's response letter was received
Nov 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Jan 2016	The company's response letter was received.
March 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2016	The company's response letter was received.
July 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2016	The company's response letter was received.
Sept 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
Dec 2016	Product dossier accepted (quality assurance)
28 Nov 2017	[HA657 trade name] was included in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory agency'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 (V), Jadcherla (M)
Mahaboobnagar 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/prequal/