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 [HA650 trade name]* (HA650) to be assessed with the aim of including [HA650 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA650 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

Sep 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Mar 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May 2015	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Jun 2015	The company's response letter letters were received.
Jul 2015	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
Nov 2015	The company's response letter was received.
Nov 2015	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
Dec 2015	The company's response letter was received.
Jan 2016	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
Jan 2016	The company's response letter was received.
May 2016	During the meeting of the assessment team the additional efficacy data and the additional quality data were reviewed and further information was requested.
Feb 2017	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Aug 2017	The company's response letter letters were received.
Sep 2017	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
Sep 2017	The company's response letter was received.
Sep & Nov 2017	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2017	The company's response letter was received.
Nov 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.

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

Nov 2017 & Jan 2018	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2018	The company's response letter was received.
Mar 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Mar 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2018	The company's response letter was received.
May 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2018	Product dossier accepted (quality assurance).
19 Jun 2018	[HA650 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 – 500055
Telangana, India

Inspection status

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

Not inspected for GLP /GCP since a biowaiver applies.

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/medicines/prequalified/finished-pharmaceutical-products