Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Ltd. submitted in 2010 an application for [HA492 trade name]* to be assessed with the aim including [HA492 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA492 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 for the assessment of the product

Sept 2010	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.
Jan 2011	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
June 2011	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
June 2011	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
Dec 2011	The company's response letter was received.
Jan 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2012	The company's response letter was received.
July 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2012	The company's response letter was received.
Sept 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2012	The company's response letter was received.
Nov 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2012	The company's response letter was received.
Dec 2012	The quality data were reviewed and found to comply with the relevant WHO requirements.
Jan 2013	Product dossier accepted (quality assurance)
11 Jan 2013	[HA492 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, Commitments 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 - 500 055
Telangana,
INDIA

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

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

2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:
http://www.who.int/prequal