Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Limited submitted in 2008 an application for [HA448 trade name] [*] to be assessed with the aim of including [HA448 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA448 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

January 2009	During the meeting of the assessment team, the quality data of the dossier were reviewed and further information was requested. The safety and efficacy data were reviewed and further information was requested.
April 2010	The company´s response letter was received.
May 2010	During the meeting of the assessment team, the additional quality, safety and efficacy data were reviewed and further information was requested.
July 2010	The company's response letter on quality was received. During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
August 2010	The company's response letter on efficacy and safety was received.
September 2010	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
January 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
February 2011	The company´s response letter on quality, efficacy and safety was received.
March 2011	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and found to be compliant with the relevant WHO requirements. During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
March 2011	The company´s response letter was received.
May 2011	During the meeting of the assessment team, the additional quality data were reviewed and found to be compliant with the relevant WHO requirements.
July 2011	Product dossier accepted (quality assurance)
01 Sept 2011	[HA448 trade name] was included in the list of prequalified medicinal products.

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, 22-110

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

(Hetero Labs Limited), HA448
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Email: contact@heterodrugs.com

Commitments for Prequalification

None.

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP. Not inspected for GCP/GLP due to previously demonstrated compliance.

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/