Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2012 an application for [HA537 trade name] * to be assessed with the aim of including [HA537 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA537 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

August 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
April 2012	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
May 2012	During the meeting of the assessment team the quality data were reviewed and further information was requested.
July 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.
September 2012	The company's response letter was received.
September 2012	During the meeting of the assessment team the safety and efficacy data and the additional quality data were reviewed and further information was requested.
November 2012	The company's response letters were received.
November 2012	During the meeting of the assessment team the additional 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.
December 2012	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
January 2013	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
January 2013	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2013	The company's response letter was received.
March 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2013	The company's response letter was received.
April 2013	The quality data were reviewed and found to comply with the relevant WHO requirements
June 2013	Product dossier accepted (quality assurance)

* Trade names are not prequalified by WHO. This is the national regulatory authority´s responsiblity.

14 June 2013	[HA537 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:

Micro Labs Limited
Plot No: S-155 to S-159 & N1,
Phase III & Phase IV,
Verna Industrial Estate, Verna,
Goa- 403722
India
Tel: +91-832- 6686262
Fax: +91-832- 6686203

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP. Not inspected for GCP/GLP. No bioequivalence study was required due to the pharmaceutical formulation.

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/