I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Ltd submitted in 2014 an application for [HA644 trade name]* to be assessed with the aim of including [HA644 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA644 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	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Sept 2014	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Jan 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
March 2015	The company's response letter was received.
March 2015	During the meetings of the assessment team the quality data and the additional efficacy data were reviewed and further information was requested.
Sept 2015	The company's response letter was received.
Sept 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2016	The company's response letters were received.
Jan 2016	During the meeting of the assessment team the additional quality and efficacy data were reviewed and further information was requested.
March 2016	The company's response letter was received.
April 2016	The company's response letter was received.
May 2016	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.
June 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 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.
Sept 2016	The company's response letter was received.
Sept 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
Oct 2016	Product dossier accepted (quality assurance)
26 Oct 2016	[HA644 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:

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

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.
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