Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2014 an application for [HA631 trade name]* (HA631) to be assessed with the aim of including [HA631 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA631 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	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Oct 2014	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Oct 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Sept and Dec 2014	The quality data were reviewed and further information was requested.
March 2015	The company's response letter was received.
March 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2015	The company's response letter was received.
Nov 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2015	In between the meetings of the assessment team the company's response letter was received. The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2015	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Dec 2015	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
March 2016	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
April 2016	Product dossier accepted (quality assurance)
27 May 2016	[HA631 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 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 & IV

Verna Industrial Estate Verna, Goa- 403722

India

Inspection status

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

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