Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs limited submitted in 2016 an application for [HA674 trade name]* (HA674) to be assessed with the aim of including [HA674 trade name] in the list of prequalified medicinal products for treatment of HIV/AIDS.

[HA722 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

July 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Aug 2016	The company's response letter was received.
Sept 2016	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
July 2016 and Sept 2016	During the meetings of the assessment team the quality data were reviewed and further information was requested.
Nov 2016	The company's response letters were received.
Nov 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.
Jan 2017	The company's response letter was received.
Jan 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
Feb 2017	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2017	Product dossier accepted (quality assurance)
30 June 2017	[HA674 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 (ML06)
Plot No: S-155 to S-159 & N1, Phase III & Phase IV
Verna Industrial Estate, Verna
Goa- 403722
India

Inspection status

The sites inspected were found to be compliant 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/