STEPS TAKEN FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2014 an application for [HA629 trade name]* to be assessed with the aim of including for [HA629 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA629 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

July2014	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
August 2014	The applicant's response letter was received.
September 2014	During the meeting of the assessment team the quality data and the additional efficacy data were reviewed and further information was requested.
January 2015	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
June 2015	The applicant's response letter was received.
July 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2015	The applicant's response letter was received.
November 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2016	The applicant's response letter was received.
March 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2016	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
April 2016	The applicant'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.
February 2017	The manufacturer of two APIs was inspected for compliance with WHO requirements for GMP.
July and August 2017	The applicant's response letters were received.
September 2017	During the meeting of the assessment team the additional quality and efficacy data were reviewed and further information was requested.
November 2017	The applicant's response letter was received.
November 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2017	The applicant's response letters were received.
January 2018	During the meeting of the assessment team the additional quality and efficacy data were reviewed and further information was requested.
February 2018	The applicant's response letter was received.
March 2018	The safety and efficacy data were reviewed and found to comply with the relevant

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility.

	WHO requirements.
August 2018	A desk review for evaluation of compliance of the manufacturer of two APIs for GMP was conducted and it met WHO requirements.
November 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
December 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
February 2019	The applicant's response letter was received.
February 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2019	The applicant's response letter was received.
March 2019	The quality data were reviewed and found to comply with the relevant WHO requirements
April 2019	Product dossier accepted (quality assurance)
04 May 2019	[HA629 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, Salcette
Goa-403722
India

Commitments for Prequalification

None which have an impact on the benefit-risk profile of the medicinal product.

Inspection status

One active pharmaceutical ingredient manufacturing site and the finished pharmaceutical product manufacturing site were found to be in compliance with WHO requirements for GMP.

A desk review for evaluation of compliance of the manufacturers of the other two APIs for GMP was conducted and it met WHO requirements.

The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.

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/