I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Micro Labs Limited submitted in 2014 an application for Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets* (HA631) to be assessed with the aim of including Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets in the list of prequalified medicinal products for the treatment of HIV/AIDS.

Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets 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. The countries of origin of the assessors involved with Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets were Germany, Ghana, the Netherlands, Nigeria, South Africa, Switzerland, Tanzania and Uganda.

Licensing status:
Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets has been licensed / registered in India.

1. 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	Emtricitabine/Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets 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. Throughout this WHOPAR the proprietary name is given as an example only.

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 & IV
Verna Industrial Estate
Verna, Goa- 403722
India

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 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