I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2011 an application for [HA518 trade name] * (HA518) to be assessed with the aim of including [HA518 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA518 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

October 2007	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
February 2011	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
August 2011	The manufacturer of one of the APIs was inspected for compliance with WHO requirements for GMP.
September 2011	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
September 2011 December 2011	The quality data were reviewed and further information was requested.
November 2012	The applicant's response letter was received.
November 2012	During the meeting of the assessment team the additional quality data were reviewed an further information was requested.
June 2013	The applicant's response letter was received.
July 2013	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2013	The sites relevant for the bioequivalence study were inspected for compliance with WH requirements for GLP/GCP.
August 2013	The applicant's response letter was received.
September 2013	During the meeting of the assessment team the additional quality data were reviewed an further information was requested.
December 2013	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
December 2013	Product dossier accepted (quality assurance)
08 January 2014	[HA518 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 (NMRA) responsibility.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Cipla Ltd,
Manufacturing Division Plot No. A – 33/1/2
Patalganga Industrial Area,
District – Raigad
410220 Patalganga
Maharashtra, India.
Tel: 91 2192 250811
Fax: 91 2192 250819
E-mail: ciplaptg@cipla.com

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products