Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2006 an application for [HA354 trade name]* (HA354) to be assessed with the aim of including [HA354 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA354 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 2005	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
March 2006	During the meeting of the assessment team, safety and efficacy data of the dossier were reviewed and further information was requested.
April 2006	The company's response was received
May 2006	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
October 2006	One manufacturer of the API was inspected for compliance with WHO requirements for GMP.
November 2006	The company's response was received.
November 2006	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
May 2007	The company's response was received
July 2007	During the meeting of the assessment team, the quality data were reviewed and further information was requested.
July 2007	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
February 2008	The company's response was received
March 2008	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
June 2008	The company's response was received.
September 2008	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
September 2009	The company's response was received.
September 2009	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
February 2010	The company's response was received.
March 2010	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.

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

June 2010	The company's response was received.
July 2010	During the meeting of the assessment team, the additional data were reviewed and found to be in compliance with the relevant WHO requirements
September 2010	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
29 September 2010	[HA354 trade name] was included in the list of prequalified medicinal products

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Cipla Ltd
Unit III, IV, VII
Verna Industrial Estate
Verna Salcette
Goa
403722
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for 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