Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd. submitted in 2003 an application for [HA200 trade name]* (HA200) to be assessed with the aim of including [HA200 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA200 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

June 2005	One site of the manufacturer of the API was inspected for compliance with WHO requirements for GMP.
October 2006	One site of the manufacturer of the API was inspected for compliance with WHO requirements for GMP.
January 2003	During the meeting of the assessment team, quality, safety and efficacy data of the dossier were reviewed and further information was requested.
March 2003	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
March 2003	During the meeting of the assessment team, the quality data were reviewed and further information was requested.
May 2003	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
November 2003	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
December 2003	The company's response letter was received.
March 2004	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
April/May 2004	The company's response letters were received.
May 2004	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
May 2006	The company's response letter was received.
July 2006	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
November 2006	The company's response letter was received.
November 2006	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
December 2006	The company's response letter was received.

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

January 2007	The additional safety and efficacy data were reviewed and found to be in compliance with the relevant WHO requirements.
January 2007	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
April 2007	The company's response letter was received.
February/May 2007	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
July 2007	The company's response letter was received.
July 2007	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
August 2007	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
February 2008	The company's response letter was received.
March 2008	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
May 2008	The company's response letter was received.
May 2008	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
November 2008	The company's response letter was received.
November 2008	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
February 2009	The company's response letter was received.
March 2009	The additional quality data were reviewed and found to be in compliance with the relevant WHO requirements.
25 May 2009	[HA200 trade name] was included in the list for prequalified medicines.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Cipla Limited, Unit-1 Verna Industrial Estate, Verna, Salcette 403 722, Goa, India

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP 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