Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2005 an application for [HA352 trade name][*] (HA352) to be assessed with the aim of including [HA352 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA352 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

May 2005	The 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 reviewe and further information was requested.
May 2006	The site relevant for the bioequivalence study was inspected for compliance with WHO requirements for GCP.
May 2006	During the meeting of the assessment team, the additional safety and efficacy data of the dossie were reviewed and further information was requested.
August 2006	The company's response letter was received.
September 2006	During the meeting of the assessment team, the additional safety and efficacy data of the dossie were reviewed and further information was requested.
November 2006	The company's response letter was received.
January 2007	During the meeting of the assessment team, the additional safety and efficacy data of the dossie were reviewed and further information was requested.
May/July 2007	During the meeting of the assessment team, the 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.
November 2007	The company's response letter was received.
November 2007/ January 2008	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
April 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.
July 2008	The company's response letter was received.
September/ November 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 found to be in compliance with the relevant WHO requirements.
December 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.
16 December 08	[HA352 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 responsibility.

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
Goa Plot L139 to L146 & L147 to L147-1
Verna Industrial Estate,
Verna, Salcete - Goa
403 722 GOA
India

Commitments

None

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

2. 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