Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2006 an application for [HA353 trade name][*] (HA353) to be assessed with the aim of including [HA353 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA353 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.
May 2008	The company's response was received.
May 2008	During the meeting of the assessment team, the additional safety and efficacy data were reviewed and further information was requested.
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.
August 2009	The company's response was received.

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

September 2009	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.
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.
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	[HA353 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 Salcete
Goa 403 722
India

Cipla Ltd
C/o Meditab Specialities Ltd.
352 Kundaim Industrial Estate
Kundaim
Goa 403 115
India

Inspection status

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

Not inspected for GCP/GLP since a biowaiver applies.

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