Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd submitted in 2011 an application for [HA510 trade name]* (HA510) to be assessed with the aim of including [HA510 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA510 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

Feb 2011	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Feb 2011	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
July 2011	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Sept 2011	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Nov 2011	The company's response letter was received.
Nov 2011	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Feb 2012	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP/GLP.
Nov 2012	The company's response letter was received.
Nov 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2013	The company's response letter was received.
May 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2013	The company's response letter was received.
Nov 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2014	The company's response letter was received.
Jan 2014	The quality data were reviewed and found to comply with the relevant WHO requirements.
Feb 2014	Product dossier accepted (quality assurance)
19 Feb 2014	[HA510 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 Limited
Unit II, A-42, MIDC,
Patalganga, Dist: Raigad
410220, Maharashtra
India

Cipla Limited
Unit I, A-33 & A-37/2/2, MIDC
Patalganga, District: Raigad
410220, Maharashtra,
India

Inspection status

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

Not inspected for GCP (biowaiver).

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/prequal/