Steps taken for prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2013 an application for [HA593 trade name][1] (HA593) to be assessed with the aim of including [HA593 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA593 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 2013	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Sept 2013	The company's response letter was received.
Sept 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Jan 2014	The company's response letter was received.
Feb 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2014	The manufacturer of the APIs were inspected for compliance with WHO requirements for GMP.
August 2014	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Sept 2014	The manufacturer of the APIs were inspected for compliance with WHO requirements for GMP.
Sept 2014	The company's response letter was received.
Sept 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2014	The company's response letter was received.
Nov 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2015	The company's response letter was received.
Jan 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2015	The company's response letter was received.
April 2015	The quality data were reviewed and found to comply with the relevant WHO requirements
April 2015	Product dossier accepted (quality assurance)
16 April 2015	[HA593 trade name] was included in the list of prequalified medicinal products.

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

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release

Cipla limited
Unit II, A-42, MIDC
Patalganga
District-Raigad
Maharashtra
India

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

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

Not inspected for GLP/GCP. Previous site inspections by WHO showed acceptable outcome.

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/