Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd submitted in 2016 an application for [HA666 trade name] [*] to be assessed with the aim of including [HA666 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA666 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 for the assessment of the product

February 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2014	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
September 2014	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
May 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May 2016 and July 2016	During the meetings of the assessment team the quality data were reviewed and further information was requested.
June 2016	The company's response letter was received.
July 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
August 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
September 2016	The company's response letter was received.
September 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2016	The company's response letter was received.
November 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2016	Product dossier accepted (quality assurance)
21 December 2016	[HA666 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
Plot No A – 42 (Unit – II)
MIDC Patalganga
District Raigad, 410 220
Maharashtra India

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP. Not inspected for GCP/GLP. Previous site inspections by WHO were acceptable.

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/