Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2016 an application for [HA680 trade name]* (HA680) to be assessed with the aim of including [HA680 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA680 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

June 2008	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
March 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
September 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
November 2016	In between the meetings of the assessment team the company's response letter was received. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2016	During the meeting of the assessment team the quality data were reviewed and further information was requested.
January 2017	The company's response letter was received.
January 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2017	The company's response letter was received.
March 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2017	The company's response letter was received.
May 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2017	The company's response letter was received.
July 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2017	The company's response letter was received.
October 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
October 2017	Product dossier accepted (quality assurance)
24 October 2017	[HA680 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, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release

Cipla Limited Indore (Unit –IV)
Plot No 9, 10 & 15
Indore Special Economic Zone, Phase II
Pithampur, District: Dhar
Madhya Pradesh – 454 775
India.

Commitments for Prequalification

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

Inspection status

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

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/