Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2018 an application for [HA702 trade name] * (HA702) to be assessed with the aim of including [HA702 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA702 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

September 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
March 2016	The manufacturer of two APIs was inspected for compliance with WHO requirements for GMP.
June 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
April 2018	The applicant's response letter was received.
May 2018	During the meeting of the assessment team the quality data were reviewed and further information was requested.
May 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2018	The applicant's response letter was received.
August 2018	The additional quality data were reviewed and further information was requested.
September 2018	The applicant's response letter was received.
September 2018	During the meeting of the assessment team the quality data were reviewed and further information was requested.
November 2018	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP was conducted and it met WHO requirements.
November 2018	The applicant's response letter was received.
March 2019	During the meeting of the assessment team the quality data were reviewed and further information was requested.
March 2019	The applicant's response letter was received.
March 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2019	Product dossier accepted (quality assurance)
05 April 2019	[HA702 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 Limited
Unit VII PD II
Verna Industrial Estate
Verna, Salcette

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

Goa-403 722
India

Inspection status

The active pharmaceutical ingredient and finished pharmaceutical product manufacturing sites were found to be in compliance with WHO requirements for GMP.
A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP was conducted and it met WHO requirements.

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