Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2019 an application for [HA743 trade name]* (HA743) to be assessed with the aim of including [HA743 trade name] in the list of prequalified medicinal products for treatment of HIV/AIDS.

[HA743 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

April 2019	The manufacturer of two APIs was inspected for compliance with WHO requirements for GMP.
September 2019	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
October 2019	The assessment team reviewed the quality data and further information was requested.
November 2019	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
November 2019	The applicant's response letters were received.
November 2019	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2019	The applicant's response letters were received.
November and December 2019	The assessment team reviewed the additional quality data and further information was requested.
February 2020	The applicant's response letter was received.
March 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2020	A desk review for evaluation of compliance for the bioequivalence study for GLP/GCP met WHO requirements.
October 2020	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
August 2022	The applicant's response letter was received.
September 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2022	The applicant's response letter was received.
November 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2023	The applicant's response letter was received.

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

January and February 2023	The assessment team reviewed the additional quality data and further information was requested.
February 2023	The applicant's response letter was received.
February 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2023	Product dossier accepted (quality assurance)
10 March 2023	[HA743 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 2, Plot No A – 42
MIDC Industrial Area
Patalganga
District Raigad
Maharashtra 410 220
India.

Cipla Limited
Unit 7, Plot No. S- 103 to S- 105
S-107 to S-112, L-147
L-147/1 to L-147/3
L-147/A & L-138
Verna Industrial Estate
Salcette
Goa – 403 722
India.

Inspection status

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

A desk review for evaluation of compliance for the bioequivalence study for GLP/GCP met WHO requirements.

A desk review for evaluation of compliance of the manufacturer of the FPP for GMP 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