Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd submitted in 2021 an application for [HA770 trade name]* (HA770) to be assessed with the aim of including [HA770 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA770 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

January 2019	The manufacturers of two APIs were inspected for compliance with WHO requirements for GMP.
August 2019	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
October 2020	A desk review for evaluation of compliance of one manufacturer of the FPP for GMP was conducted and it met WHO requirements.
September 2021	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
November 2021	The applicant's response letter was received.
November 2021	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
October and December 2021	The quality data were reviewed, and further information was requested.
March 2022	The applicant's response letter was received.
March and May 2022	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
July 2022	The applicant's response letter was received.
August 2022	The additional quality data were reviewed, and further information was requested.
September 2022	One manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2022	The applicant's response letter was received.
January 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
January 2023	Product dossier accepted (quality assurance).
March 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
02 May 2023	[HA770 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
Maharashtra 410 220
India

Cipla Quality Chemical Industries Limited (Cipla QCIL)
Plot 1-7 1st Ring Road, Luzira Industrial Park
P O Box 34871
Kampala, Uganda

Inspection status

The manufacturer of one FPP was inspected and found to be in compliance with WHO requirements for GMP.

The manufacturer of one FPP inspection was based on WHO desk assessment and found to be in compliance with WHO requirements for GMP.

The manufacturers of two APIs were inspected and found to be in compliance with WHO requirements for GMP.

The manufacturer of one API inspection was based on WHO desk assessment and found to be in compliance with WHO requirements for GMP.

The sites inspected for GCP and GLP were found to be in compliance with WHO requirements for GCP and 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products