Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2019 an application for [HA741 trade name]* (HA741) to be assessed with the aim of including [HA741 trade name] in the list of prequalified medicinal products for treatment of human immunodeficiency virus (HIV) infection.

[HA741 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 manufacturer of the API 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.
July and October 2019	The quality data were reviewed and further information was requested.
November 2019	The applicant's response letters were received.
November 2019	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
December 2019	The additional quality data were reviewed and further information was requested.
October 2020	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
January 2021	The applicant's response letter was received.
January 2021	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
February 2021	The additional quality data were reviewed and further information was requested.
March 2021	The applicant's response letters were received.
March 2021	During the meeting of the assessment team the additional quality data and safety and efficacy data were reviewed and further information was requested.
April 2021	The applicant's response letter was received.
May 2021	The applicant's response letter was received.
May 2021	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May and August 2021	The additional quality data were reviewed and further information was requested.
October 2021	The applicant's response letter was received.

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

November 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2021	The applicant's response letter was received.
November 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2021	Product dossier accepted (quality assurance).
30 November 2021	[HA741 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

Plot No A – 42 (Unit – II)

MIDC Patalganga

District Raigad

Maharashtra 410 220

India

Inspection status

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

Not inspected for GCP/GLP since a biowaiver applies.

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/medicines/prequalified/finished-pharmaceutical-products