Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2022 an application for [HA779 trade name]* (HA779) to be assessed with the aim of including [HA779 trade name] in the list of prequalified medicinal products for treatment of HIV-1 infection in infants and children aged from 4 weeks and weighing 6 to 25 kg.

[HA779 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 2020	A desk review for evaluation of compliance of the manufactures of APIs for GMP was conducted and it met WHO requirements.
June 2021	A desk review for evaluation of compliance of the manufactures of the API for GMP was conducted and it met WHO requirements.
September 2022	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
September and November 2022	During the meetings of the assessment team the 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 safety and efficacy data were reviewed and further information was requested.
December 2022	The applicant's response letter was received.
January 2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
February 2023	The applicant's response letter was received.
April 2023	The additional quality data were reviewed and further information was requested.
June 2023	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
June 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2023	The applicant's response letter was received.
October 2023	The additional quality data were reviewed and further information was requested.

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

October 2023	The applicant's response letter was received.
November 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2023	Product dossier accepted (quality assurance)
16 November 2023	[HA779 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, Indore Unit IV
Plot No. 9 and 10 Indore Special Economic Zone,
Phase II, Pithampur,
District Dhar,
454775, Madhya Pradesh,
India

Inspection status

The FPP manufacturer and CRO inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

API manufacturers accepted based on desk assessment.

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