Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Shouguang Fukang Pharmaceutical Company Limited submitted in 2022 an application for [HA775 trade name][*] (HA775) to be assessed with the aim of including [HA775 trade name] in the list of prequalified medicinal products for the treatment and prevention of infections in HIV/AIDS patients.

[HA775 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

May 2022	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
June 2022	The applicant's response letter was received.
July 2022	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
May and August 2022	The assessment team reviewed the quality data and further information was requested.
August 2022	The applicant's response letter was received.
September 2022	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
October 2022	The applicant's response letter was received.
November 2022	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
December 2022	The applicant's response letter was received.
January and February 2023	The additional quality data were reviewed and further information was requested.
March 2023	The applicant's response letter was received.
April 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
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.
November 2023	The applicant's response letter was received.
November 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2023	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
December 2023	Product dossier accepted (quality assurance)
18 December 2023	[HA775 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

Shouguang Fukang Pharmaceutical Company Limited

No. 999, Wensheng East Street

Shouguang City,

Shandong- 262700

China

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GLP and GCP.

Not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

API supported by a CEP. Inspection of the manufacturing site waived based on previous satisfactory inspection by a stringent regulatory authority.

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