

## 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>