Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Shanghai Desano Bio-Pharmaceutical Co., Ltd submitted in 2023 an application for [HA787 trade name][*] (HA787) to be assessed with the aim of including [HA787 trade name] in the list of prequalified medicinal products for treatment of HIV.

[HA787 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

July 2023	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
September 2023	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
September and October 2023	The quality data were reviewed by the assessment team and further information was requested.
November 2023	In between the meetings of the assessment team the applicant's response letter was received. The additional /safety and efficacy data were reviewed and further information was requested.
January 2024	In between the meetings of the assessment team the applicant's response letter was received. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2024	The applicant's response letter was received.
January 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2024	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2024	The applicant's response letter was received.
March and April 2024	The additional quality data were reviewed and further information was requested.
May 2024	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2024	The applicant's response letter was received.
June 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2024	Product dossier accepted (quality assurance)
02 July 2024	[HA787 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

Shanghai Desano Bio-Pharmaceutical Co., Ltd.
1479 Zhangheng Road
China (Shanghai) Pilot Free Trade Zone
Shanghai 201203
P.R. China

Inspection status

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

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