Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Shanghai Desano Bio-Pharmaceutical Co Ltd submitted in 2017 an application for [HA694 trade name]* (HA694) to be assessed with the aim of including [HA694 trade name] in the list of prequalified medicinal products for the treatment of HIV infection.

[HA694 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

September 2017	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.
November 2017	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
November and December 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested.
January 2018	The applicant's response letter was received.
January 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
February 2018	The applicant's response letter was received.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2018	The applicant's response letter was received.
May 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2018	The applicant's response letter was received.
July + September 2018	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
August 2018	The applicant's response letter was received.
September 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2018	The applicant's response letter was received.
November 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2019	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.

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

March 2019	The applicant's response letters were received.
March 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2020	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
October 2020	The applicant's response letter was received.
October 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2019	Product dossier accepted (quality assurance)
2 November 2020	[HA694 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

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

Inspection status

A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.

A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.

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