Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs submitted in 2020 an application for [HA759 trade name]* (HA759) to be assessed with the aim of including [HA759 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA759 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

October 2019	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
July 2020	During the meeting of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September 2020	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.
September 2020	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
November 2020	The applicant's response letter was received.
November 2020 and January 2021	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
February 2021	The applicant's response letter was received.
March 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2021	The applicant's response letter was received.
July 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2021	The applicant's response letter was received.
September 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2021	The applicant's response letter was received.
November 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2021	The applicant's response letter was received.
January and March 2022	During the meetings of the assessment team 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.

March 2022	The applicant's response letter was received.
April 2022	The additional quality data were reviewed and further information was requested.
May 2022	The applicant's response letter was received.
May 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2022	Product dossier accepted (quality assurance)
28 June 2022	[HA759 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

Hetero Labs Limited, Unit-V
Survey No. 439, 440, 441 & 458,
TSIIC-Formulation SEZ, Polepally Village,
Jadcherla (Mandal), Mahaboob Nagar District
Telangana State,
509 301, India

Inspection status

Not inspected for GMP/GLP /GCP. Previous site inspections by WHO were acceptable.

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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products