Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited submitted in 2019 an application for [HA737 trade name][*] (HA737) to be assessed with the aim of including [HA737 trade name] in the list of prequalified medicinal products for treatment of HIV.

[HA737 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

June 2019	The safety and efficacy data were reviewed and further information was requested
July 2019	The applicant's response letter was received.
July 2019	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 2019	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
November 2019	The applicant's response letter was received.
November and December 2019	The additional quality data were reviewed and further information was requested.
February 2020	The applicant's response letter was received.
March and May 2020	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
June 2020	A desk review for evaluation of compliance of the manufacturer of two APIs for GMP was conducted and it met WHO requirements.
July 2020	The applicant's response letter was received.
July 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2020	A desk review for evaluation of compliance of the manufacturer of two APIs for GMP was conducted and it met WHO requirements.
August 2020	The applicant's response letter was received.
September and November 2020	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
January 2021	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2021	The applicant's response letter was received.

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

February 2021	The additional quality data were reviewed and further information was requested.
April 2021	The applicant's response letter was received.
May 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.
December 2021	The applicant's response letter was received.
January 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2022	The applicant's response letter was received.
May 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
June 2022	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
June 2022	The applicant's response letter was received.
July and October 2022	The additional quality data were reviewed and further information was requested.
October 2022	The applicant's response letter was received.
November 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2022	The applicant's response letter was received.
November 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2022	Product dossier accepted (quality assurance)
09 December 2022	[HA737 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

Lupin Limited
Plot No. 6A1, 6A2, Sector-17
Special Economic Zone
MIHAN Notified Area
Nagpur
Maharashtra-441108
India

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