Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Lupin Limited, Mumbai, India submitted in 2018 an application for [HA720 trade name][*] (HA720) to be assessed with the aim of including [HA720 trade name] in the list of prequalified medicinal products for the treatment of HIV-1 infected adults and children weighing at least 25 kg, in combination with other antiretroviral medicinal products

[HA720 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

February 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP.
July and September 2018	During the meetings of the assessment team the quality data were reviewed and further information was requested.
September 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
October 2018	The applicant's response letter was received.
November 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2019	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
May 2019	The applicant's response letter was received.
July 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 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.
December 2019	The additional quality data were reviewed and further information was requested.
March 2020	The applicant's response letter was received.
March 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2020	The applicant's response letter was received.
May 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2020	The applicant's response letter was received.

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

September 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2021	The applicant's response letter was received.
January 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 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.
May 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.
July 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.
October 2021	The applicant's response letter was received.
October and December 2021	The additional quality data were reviewed and further information was requested.
January 2022	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2022	The applicant's response letter was received.
March 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2022	The applicant's response letter was received.
April 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2022	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
May 2022	Product dossier accepted (quality assurance)
04 May 2022	[HA720 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 (Unit 1)
Plot No. 6A, 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