Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2020 an application for [HA754 trade name]* (HA754) to be assessed with the aim of including [HA754 trade name] in the list of prequalified medicinal products for the treatment of fungal infections.

[HA754 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

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

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

July 2021	The applicant's response letter was received.
August 2021	The additional quality data were reviewed and further information was requested.
August 2021	The applicant's response letter was received.
September 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
September 2021	Product dossier accepted (quality assurance).
29 September 2021	[HA754 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

Mylan Laboratories Limited

Plot No. 11, 12 & 13 Indore Special Economic Zone

Pharma Zone, Phase – II, Sector – III

Pithampur – 454775, Dist. Dhar

Madhya Pradesh

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