Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2021 an application for [HA769 trade name][*] (HA769) to be assessed with the aim of including [HA769 trade name] in the list of prequalified medicinal products for the treatment of fungal infections.

[HA769 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

July 2021	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
August 2021	The applicant's response letter was received.
September 2021	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
July and October 2021	The quality data were reviewed by the assessment team and further information was requested.
October 2021	The applicant's response letter was received.
November 2021	During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested.
November 2021	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
December 2021	The applicant's response letter was received.
January 2022	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2022	The applicant's response letter was received.
January and February 2022	The additional quality data were reviewed and further information was requested.
April 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.
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.
January 2023	The applicant's response letter was received.
January 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
March 2023	The applicant's response letter was received.

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

March 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2023	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2024	The applicant's response letter was received.
April 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
April 2024	Product dossier accepted (quality assurance)
25 April 2024	[HA769 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

Macleods Pharmaceuticals Limited
Plot No.50 to 54A
SEZ, Phase II
Pithampur
Dist.: Dhar
Madhya Pradesh, 454774
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/prequal/medicines/prequalified/finished-pharmaceutical-products