Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2020 an application for [TB383 trade name][*] (TB383) to be assessed with the aim of including [TB383 trade name] in the list of prequalified medicinal products for the treatment and prevention of isoniazid-induced peripheral neuropathy in patients at risk of the condition and also for prevention of isoniazid toxicity in children receiving high dose isoniazid regimens.

[TB383 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

March 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March and April 2020	During the meeting of the assessment team the quality data were reviewed and further information was requested.
July 2020	The applicant's response letter was received.
September 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2020	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
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.
June 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	The applicant's response letter was received.
September and December 2021	The additional quality data were reviewed and further information was requested.
March 2022	The applicant's response letter was received.
April 2022	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.

April 2022	The applicant's response letter was received.
April 2022	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	Product dossier accepted (quality assurance)
13 May 2022	[TB383 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
Unit 2, Plot No. 25-27
Survey No 366
Premier Industrial Estate
Kachigam
Daman, 396 210

India Inspection status

API supported by a CEP. Inspection of the manufacturing site waived based on risk assessment.

FPP manufacturer not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

Not inspected for GCP/GLP since a biowaiver applies

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