I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2015 an application for Rifampicin/Isoniazid/Pyrazinamide 75mg/50mg/150mg Dispersible Tablets [1] (TB309) to be assessed with the aim of including Rifampicin/Isoniazid/Pyrazinamide 75mg/50mg/150mg Dispersible Tablets in the list of prequalified medicinal products for the treatment of tuberculosis.

Rifampicin/Isoniazid/Pyrazinamide 75mg/50mg/150mg Dispersible Tablets 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.

Licensing status:
Rifampicin/Isoniazid/Pyrazinamide 75mg/50mg/150mg Dispersible Tablets has been licensed / registered in the following countries:

Country	Registration numbers
Ethiopia	MAC/IND/710
Kenya	H2015/CTD3548/606
Uganda	10084/06/17
Ivory Coast	E-2015-250
Mozambique	4566

2. Steps taken in the evaluation of the product

March 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
March and May 2015	During the meeting of the assessment team the quality data were reviewed and further information was requested.
July 2015	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Sept 2015	The company's response letter was received.
Nov 2015	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Nov 2015	The company's response letter was received.
Nov 2015	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
Dec 2015	The company's response letter was received.
Jan 2016	During the meeting of the assessment team the additional quality and additional efficacy da were reviewed and further information was requested.
Feb and March 2016	The company's response letters were received.
March 2016	During the meeting of the assessment team the additional 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.

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

April 2016	The company's response letter was received.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2016	The company's response letter was received.
July 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2016	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Sept 2016	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
Dec 2016	Due to concerns regarding GCP compliance, a new bioequivalence study was submitted. The safety and efficacy data were reviewed and further information was requested.
April 2017	The company's response letter was received.
May 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2017	The company's response letters were received.
July 2017	During the meeting of the assessment team the additional quality and efficacy data were reviewed and further information was requested.
July 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Aug 2017	The manufacturers of one API were inspected for compliance with WHO requirements for GMP.
Aug 2017	The company's response letters were received.
Aug 2017	The additional quality data were reviewed and further information was requested.
Sept 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Sept 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2017	The company's response letters were received.
Nov 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
Dec 2017	Product dossier accepted (quality assurance)
12 Dec 2017	Rifampicin/Isoniazid/Pyrazinamide 75mg/50mg/150mg Dispersible Tablets was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Macleods Pharmaceuticals Limited
Phase II, Unit II
Plot No 25-27, Survey No 366
Premier Industrial Estate
Kachigam, Daman, 369 210
India

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

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

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/