I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2014 an application for Terizidone Capsules 250 mg [1] (TB303) to be assessed with the aim of including Terizidone Capsules 250 mg in the list of prequalified medicinal products for the treatment of tuberculosis.

Terizidone Capsules 250 mg 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:
Terizidone Capsules 250 mg has been licensed / registered in the following countries:

Country	Registration Number
Botswana	BOT1803229

2. Steps taken in the evaluation of the product

Jan 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
March 2015	The company's response letter was received.
March 2015	During the meeting of the assessment team the 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.
April 2015	The company's response letter was received.
May 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2015	The company's response letter was received.
July2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2015	The company's response letter was received.
Sept 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2015	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
Jan 2016	The company's response letter was received.
Jan 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2016	The company's response letter was received.
March 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 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.
Aug 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.

[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.

Sept 2016	The company's response letter was received.
Nov 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2016	The company's response letter was received.
Jan 2017	During the meeting of the assessment team the additional quality 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	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
Oct 2017	The company's response letter was received.
Nov 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
Nov 2017	Product dossier accepted (quality assurance)
28 Nov 2017	Terizidone Capsules 250 mg 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
Unit II, Plot No. 25 – 27, Survey No. 366
Premier Industrial Estate
Kachigam
Daman – 396210
India
Tel: +91-260-2240125
Fax: +91-260-2241565

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/