## Steps before prequalification

# I. BACKGROUND INFORMATION ON THE PROCEDURE

## 1. Submission of the dossier

The company Macloeds Pharmaceutical Ltd submitted in 2016 an application for [TB333 trade name][*] (TB333) to be assessed with the aim of including [TB333 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB333 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

| | |
|---|---|
| May 2014 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. |
| Nov 2015 | One manufacturer of the API was inspected for compliance with WHO requirements for GMP. |
| July 2016 | During the meeting of the assessment team the additional <quality> <efficacy> data were reviewed and further information was requested. |
| Aug 2016 | One manufacturer of the API was inspected for compliance with WHO requirements for GMP. |
| Aug and Sept 2016 | The company's response letters were received. |
| Sept 2016 | During the meeting of the assessment team the quality data were reviewed and further information was requested.<br>The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements. |
| Dec 2016 | The company's response letter was received. |
| Jan 2017 | During the meeting of the assessment team the quality data were reviewed and further information was requested. |
| Feb 2017 | The company's response letter was received. |
| March 2017 | The quality data were reviewed and found to comply with the relevant WHO requirements. |
| May 2017 | Product dossier accepted (quality assurance) |
| 30 May 2017 | [TB333 trade name] was included in the list of prequalified medicinal products. |

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

# II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

## 1. Manufacturer 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, 396 210
India

**Inspection status**

The sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for GCP/GLP. Previous inspections by WHO 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products