## Steps before prequalification

# I. BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd submitted in 2013 an application for [TB278 trade name][*] (TB278) to be assessed with the aim of including [TB278 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB278 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

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| Feb 2012 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP |
| March 2012 | The manufacturer of the API was inspected for compliance with WHO requirements for GMP |
| Feb 2013 | The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP/GCP. . |
| July 2013 | 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. |
| Nov 2013 | The applicant's response letters were received. |
| Nov 2013 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested |
| Dec 2013 | The company's response letter was received. |
| Jan 2014 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested |
| Feb 2014 | The applicant's response letters were received. |

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

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| March 2014 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested |
| April 2014 | The applicant's response letters were received. |
| May 2014 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested<br>. |
| Sept 2014 | The applicant's response letters were received. |
| Oct 2014 | The quality data were reviewed and found to comply with the relevant WHO requirements |
| Oct 2014 | Product dossier accepted (quality assurance) |
| 24 Oct 2014 | [TB278 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
Block-N2
Village Theda
Post Office Lodhimajra
Tehsil Baddi
District Solan
Himachal Pradesh – 174101
India

**Inspection status**

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

Not inspected for GMP/GLP /GCP. Previous site inspections by WHO were acceptable

### 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