## Steps before prequalification

# I. BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company Macleods Pharmaceuticals Ltd. submitted in 2018 an application for [TB361 trade name][*] (TB361) to be assessed with the aim of including [TB361 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB361 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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| March 2018 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. |
| May 2018 | During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested |
| July 2018 | The applicant's response letter was received. |
| July 2018 | During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested. |
| May and July 2018 | During the meetings of the assessment team the quality data were reviewed and further information was requested. |
| August 2018 | The applicant's response letter was received. |
| September 2018 | The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements. |
| October 2018 | The applicant's response letter was received. |
| November 2018 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| February 2019 | The applicant's response letter was received. |
| March 2019 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| May 2019 | The applicant's response letter was received. |
| July 2019 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| August 2019 | The applicant's response letter was received. |
| September 2019 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| October 2019 | The applicant's response letter was received. |
| November 2019 | During the meeting of the assessment team 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.

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| January 2020 | The applicant's response letter was received. |
| January 2020 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| March 2020 | The applicant's response letter was received. |
| March 2020 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| May 2020 | The applicant's response letter was received. |
| July 2020 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| August 2020 | A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements. |
| September 2020 | The applicant's response letter was received. |
| September 2020 | The quality data were reviewed and found to comply with the relevant WHO requirements. |
| September 2020 | Product dossier accepted (quality assurance) |
| 16 September 2020 | [TB361 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

At, Oxalis Labs

G-Block,Village Theda

P.O. Lodhimajra

Tehsil Baddi, Dist. Solan

Himachal Pradesh, 174101, India

**Inspection status**

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

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/