# Steps before prequalification

## 1. BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company Macleods Pharmaceuticals Limited submitted in 2019 an application for [HA740 trade name][*] (HA740) to be assessed with the aim of including [HA740 trade name] in the list of prequalified medicinal products for in combination with other antiretroviral agents for the treatment of HIV/AIDS.

[HA740 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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| May 2019 | The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements. |
| May and July 2019 | During the meetings of the assessment team the quality data were reviewed and further information was requested. |
| August 2019 | A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements. |
| October 2019 | A desk review for evaluation of compliance of the manufacturer of two APIs for GMP was conducted and it met WHO requirements. |
| October 2019 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. |
| November 2019 | The applicant's response letter was received. |
| December 2019 | The additional quality data were reviewed and further information was requested. |
| April 2020 | The applicant's response letter was received. |
| May 2020 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| July 2020 | The applicant's response letter was received. |
| September 2020 | A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements. |
| December 2020 | The additional quality data were reviewed and further information was requested. |
| January 2021 | The applicant's response letter was received. |
| January 2021 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| February 2021 | The applicant's response letter was received. |
| February 2021 | The quality data were reviewed and found to comply with the relevant WHO requirements. |
| February 2021 | Product dossier accepted (quality assurance) |

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

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| 11 May 2021 | [HA740 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
P.O. Lodhimajra
Tehsil Baddi, Dist. Solan
Himachal Pradesh, 174101,
India

**Inspection status**

Not inspected for GMP/GLP/GCP. Previous inspections by a stringent regulatory authority were acceptable.

API manufacturer not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

Not inspected for GMP/GLP /GCP. Previous site inspections by a stringent regulatory authority 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products