## Steps before prequalification

# I. BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company Micro Labs Ltd submitted in 2020 an application for [HA763 trade name]* (HA763) to be assessed with the aim of including [HA763 trade name] in the list of prequalified medicinal products for treatment of HIV.

[HA763 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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| April 2019 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. |
| May 2019 | A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements. |
| September 2019 | A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements. |
| September 2020 | During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested |
| September 2020 | The site relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP. |
| November 2020 | The applicant's response letter was received. |
| November 2020 | The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements. |
| September and December 2020 | The quality data were reviewed and further information was requested. |
| March 2021 | The applicant's response letter was received. |
| March 2021 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested |
| July 2021 | The applicant's response letter was received. |
| September 2021 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested |
| November 2021 | The applicant's response letter was received. |
| November 2021 and January 2022 | During the meetings of the assessment team the additional quality data were reviewed and further information was requested |
| February 2022 | The applicant's response letter was received. |
| February 2022 | The quality data were reviewed and found to comply with the relevant WHO requirements. |

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

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| April 2022 | The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP / GCP. |
| March 2022 | Product dossier accepted (quality assurance) |
| 26 April 2022 | [HA763 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**

Micro Labs Limited (ML06)
Plot No S-155 to S-159 & N1, Phase III & Phase IV
Verna Industrial Estate
Verna, Goa, 403 722, India

**Inspection status**

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

## 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