## Steps before prequalification

# I. BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company Micro Labs Limited submitted in 2020 an application for [HA760 trade name]* (HA760) to be assessed with the aim of including [HA760 trade name] in the list of prequalified medicinal products for the treatment of human immunodeficiency virus (HIV) infection in adults and children weighing 35 kg or more.

[HA760 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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| July 2020 | During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested |
| September 2020 | During the meeting of the assessment team the quality data were reviewed and further information was requested. |
| November 2020 | The applicant's response letter was received. |
| November 2020 | During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested. |
| January 2021 | The applicant's response letter was received. |
| January and March 2021 | During the meetings of the assessment team the additional quality data were reviewed and further information was requested |
| April 2021 | The applicant's response letter was received. |
| May 2021 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| August 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 | During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested. |
| January 2022 | The applicant's response letter was received. |
| January 2022 | During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested. |
| February 2022 | The applicant's response letter was received. |
| March 2022 | During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested. |
| May 2022 | The applicant's response letter was received. |

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

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| July 2022 | During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested. |
| July 2022 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.<br>The analytical facilities, relevant for the acceptability of the biowaiver were inspected for compliance with WHO requirements for GMP |
| October 2022 | The manufacturer of one API was inspected for compliance with WHO requirements for GMP. |
| February 2023 | The applicant's response letters were received. |
| March 2023 | During the meeting of the assessment team the additional safety and efficacy data were reviewed and further information was requested. |
| March and April 2023 | The additional quality data were reviewed and further information was requested. |
| April 2023 | The applicant's response letters were received. |
| May 2023 | During the meeting of the assessment team the additional quality efficacy 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. |
| May 2023 | The applicant's response letter was received. |
| July 2023 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| July 2023 | The applicant's response letter was received. |
| July 2023 | The quality data were reviewed and found to comply with the relevant WHO requirements. |
| July 2023 | Product dossier accepted (quality assurance) |
| 02 September 2023 | [HA760 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

Plot No S-155 to S-159 & N1, Phase III & Phase IV,

Verna Industrial Estate,

Verna, Goa, 403 722, India

**Inspection status**

The FPP manufacturing site was inspected and found to be in compliance with WHO requirements for GMP.

The manufacturer of one of the APIs was not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

The GMP compliance of one of the API manufacturers was accepted based on WHO desk assessment.

The sites inspected were found to be in compliance with WHO requirements for 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/prequal/medicines/prequalified/finished-pharmaceutical-products