## Steps before prequalification

# I BACKGROUND INFORMATION ON THE PROCEDURE

## 1. Submission of the dossier

The company Laurus Labs Limited submitted in 2019 an application for [HA732 trade name]* to be assessed with the aim of including [HA732 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA732 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 2017 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. |
| September 2017 | The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP. |
| March 2019 | During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested. |
| March 2019 | The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP. |
| April 2019 | The applicant's response letter was received. |
| May 2019 | During the meeting of the assessment team the additional quality data were reviewed and further information was requested. |
| June 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. |
| September 2019 | The applicant's response letter was received. |
| October 2019 | The additional quality data were reviewed and further information was requested. |
| October 2019 | The applicant's response letter was received. |
| February 2020 | The additional quality data were reviewed and further information was requested. |
| February 2020 | The applicant's response letter was received. |
| February 2020 | The quality data were reviewed and found to comply with the relevant WHO requirements. |
| February 2020 | Product dossier accepted (quality assurance) |
| 16 March 2020 | [HA732 trade name] was included in the list of prequalified medicinal products. |

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

# II GENERAL CONDITIONS FOR THE PREQUALIFICATION

## 1. Manufacturer, Commitments and Inspection status

**Manufacturer of the finished product and responsible for batch release**

Laurus Labs Limited, (Unit-II)
Plot No. 19, 20 & 21
Western Sector, APSEZ
Atchutapuram Mandal
Visakhapatnam-District-531011
Andhra Pradesh
India

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

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