STEPS FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Laurus Labs Limited submitted in 2018 an application for [HA718 trade name][*] to be assessed with the aim of including [HA718 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA718 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 for the assessment of the product

March 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 2017	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
October 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
July 2018	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
August 2018	The applicant's response letter was received.
September 2018	During the meeting of the assessment team, the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 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.
January 2019	The applicant's response letter was received.
February 2019	The additional quality data were reviewed and further information was requested.
August 2019	In between the meetings of the assessment team, the applicant's response letter was received. 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.
September 2019	The applicant's response letter was received.
October 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2019	Product dossier accepted (quality assurance).
14 October 2019	[HA718 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 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

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/prequal/