Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Laurus Labs Ltd submitted in 2018 an application for [HA707 trade name][*](HA707) to be assessed with the aim of including [HA707 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA707 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

March 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 2017	The manufacturers of the APIs were 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 GCP and GLP.
May 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 2018	During the meeting of the assessment team the quality data were reviewed, and further informatio was requested.
October 2018	The applicant's response letter was received.
December 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2018	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2019	The applicant's response letter was received.
March 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2019	The applicant's response letter was received.
August 2019	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.
October 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2019	Product dossier accepted (quality assurance)
19 November 2019	[HA707 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
Gurajapalem village,
Rambilli Mandal, Anakapalli,
Andhra Pradesh 531011 India

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/medicines/prequalified/finished-pharmaceutical-products