Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Laurus Labs Limited submitted in 2018 an application for [HA709 trade name]* (HA709) to be assessed with the aim of including [HA709 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA709 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 manufacturer of the API was inspected for compliance with WHO requirements for GMP.
July 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
September 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.
September 2018	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.
December 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.
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.
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.
July 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.
November 2019	The applicant's response letter was received.
November 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2020	The applicant's response letter was received.
January and April 2020	The additional quality data were reviewed and further information was requested.
May 2020	The applicant's response letter was received.

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

May 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2020	Product dossier accepted (quality assurance)
12 June 2020	[HA709 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

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

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.
Not inspected for GCP/GLP since a biowaiver applies.

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