I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Limited submitted in 2015 an application for [HA650 trade name]* to be assessed with the aim including [HA650 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA650 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

September 2014	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
March 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May 2015	During the meeting of the assessment team the quality data were reviewed and further information was requested.
June 2015	The company's response letter letters were received.
July 2015	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
November 2015	The company's response letter was received.
November 2015	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
December 2015	The company's response letter was received.
January 2016	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
January 2016	The company's response letter was received.
May 2016	During the meeting of the assessment team the additional efficacy data and the additional quality data were reviewed and further information was requested.
February 2017	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
August 2017	The company's response letter letters were received.
September 2017	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
September 2017	The company's response letter was received.

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

September & November 2017	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
October 2017	The company's response letter was received.
November 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2017 & January 2018	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
February 2018	The company's response letter was received.
March 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2018	The company's response letter was received.
May 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2018	Product dossier accepted (quality assurance).
19 June 2018	Lopinavir / Ritonavir 100 mg/ 25 mg Tablets was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Hetero Labs Limited, Unit III
Plot No. 22-110, IDA, Jeedimetla
Hyderabad – 500055
Telangana, 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.
Not inspected for GLP /GCP 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/