PART 7: STEPS TAKEN FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Ltd submitted in 2018 an application for [HA696 trade name]* (HA696) to be assessed with the aim of including [HA696 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA696 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

October 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
January 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2018	During the meeting of the assessment team the quality data were reviewed and further information was requested.
May 2018	The applicant's response letter was received.
May 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2018	The applicant's response letter was received.
July 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2018	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
August 2018	The applicant's response letter was received.
September 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 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.
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.
August 2019	A desk review for evaluation of compliance of the manufacturer of two APIs for GMP was conducted and it met WHO requirements.
October 2019	A desk review for evaluation of compliance of the manufacturer of two APIs for GMP was conducted and it met WHO requirements.
December 2019	The additional quality data were reviewed and further information was requested.
December 2019	The applicant's response letter was received.
December 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2019	Product dossier accepted (quality assurance)
19December 2019	[HA696 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:

Hetero Labs Limited, Unit-III
Plot #22-110, IDA
Jeedimetla, Hyderabad
Telangana, 500 055
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/