STEPS TAKEN FOR PREQUALIFICATION

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Milan Laboratories (India) Pvt Ltd submitted in 2017 an application for [HA691 trade name][*] to be assessed with the aim of including [HA691 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS related conditions.

[HA691 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

July 2017	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
August 2017	The applicant's response letter was received.
September 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested.
March 2018	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.
June 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.
July 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
September 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.
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.
January 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2019	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
February 2019	The manufacturer of the FPP was inspected for compliance with WHO requirements for GM
March 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.
May 2019	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
May 2019	The applicant's response letter was received.
May 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.

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

June 2019	The applicant's response letter was received.
October 2019	The additional quality data were reviewed and further information was requested.
November 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)
17 December 2019	[HA691 trade name] 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:

Milan Laboratories (India) Pvt Ltd
Plot No. 35/36/63/64/65/67
Jawahar Coop Industrial Estate Ltd
Kamothe, Panvel
Navi Mumbai
Maharashtra 410 209
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GCP and GLP

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/