STEPS FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Ltd submitted in 2017 an application for [HA685 trade name][*] (HA685) to be assessed with the aim of including [HA685 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA685 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

April 2016	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
July 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Jan 2017	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
June 2017	The applicant's response letter was received.
July 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Aug 2017	The applicant's response letter was received.
Sept 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
Feb 2018	The applicant's response letter was received.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 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.
Nov 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP.
Nov 2018	The applicant's response letter was received.
Nov 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2018	The applicant's response letter was received.
Jan 2019 and May 2019	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
May 2019	The applicant's response letter was received.
May 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
May 2019	Product dossier accepted (quality assurance)
11 June 2019	[HA685 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:

Mylan Laboratories Limited,
Plot No. H-12 and H-13,
MIDC, Waluj Industrial Area,
Aurangabad-431136,
Maharashtra,
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/