Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2018 an application for [HA697 trade name][*] (HA697) to be assessed with the aim of including [HA697 trade name] in the list of prequalified medicinal products for the treatment of HIV/AIDS.

[HA697 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	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
November 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2018	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
April 2018	The applicant's response letter was received.
May 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
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.
December 2018	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.
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.
April 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.
July 2019	The applicant's response letter was received.
October 2019	In between the meetings of the assessment team the additional quality data were reviewed and further information was requested.
October 2019	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.

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

November 2019	The manufacturer of the second API was inspected for compliance with WHO requirements for GMP.
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.
January 2020	Product dossier accepted (quality assurance)
27 October 2020	[HA697 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

Mylan Laboratories Limited
F4 & F12, MIDC, Malegaon
Sinnar, Nashik – 422 113
Maharashtra
India

Inspection status

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