Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Ltd submitted in 2020 an application for [HA762 trade name]* (HA762) to be assessed with the aim of including [HA762 trade name] in the list of prequalified medicinal products for prevention of certain opportunistic infections in people living with HIV.

[HA762 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

February 2019	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
July 2019	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
October 2019	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
September 2020	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
September 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September and December 2020	The quality data were reviewed and further information was requested.
April 2021	The applicant's response letter was received.
May 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2021	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
July 2021	The applicant's response letter was received.
September 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2021	The applicant's response letter was received.
November 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2022	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
March 2022	The applicant's response letter was received.

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

June 2022	The quality data were reviewed and found to comply with the relevant WHO requirements.
June 2022	Product dossier accepted (quality assurance)
11 July 2022	[HA762 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
Plot No. 11,12 & 13
Special Economic Zone, Pharma Zone
Phase-II, Sector-III, Pithampur-454775
Dist. Dhar, Madhya Pradesh
India

Inspection status
The sites 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products