Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2017 an application for [HA687 trade name]* (HA687) to be assessed with the aim of including [HA687 trade name] in the list of prequalified medicinal products for the treatment of infections caused by sulfamethoxazole/trimethoprim-susceptible micro-organisms in HIV/AIDS patients.

[HA687 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

March 2017	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May 2017	The applicant's response letter was received.
June 2017	In between the meetings of the assessment team the quality data were reviewed and further information was requested.
November 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2018	The applicant's response letter was received.
January 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 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.
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.
May 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
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	The applicant's response letter was received.
February 2019	The additional quality data were reviewed and further information was requested.
February 2019	The applicant's response letter was received.
March 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2019	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
March 2019	Product dossier accepted (quality assurance).
05 April 2019	[HA687 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 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 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/medicines/prequalified/finished-pharmaceutical-products