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 [HA688 trade name]* (HA688) to be assessed with the aim of including [HA688 trade name] in the list of prequalified medicinal products for HIV/AIDS.

[HA688 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

January 2015	The manufacturer of two APIs were inspected for compliance with WHO requirements for GMP.
August 2015	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
April 2016	The manufacturer of two APIs were inspected for compliance with WHO requirements for GMP.
March 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March and June 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested.
July 2017	The manufacturer of two APIs were inspected for compliance with WHO requirements for GMP.
September 2017	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
November 2017	The company's response letter was received.
November 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2018	The company'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.
February 2018	The company's response letter was received.
May 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March and July 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2018	The company's response letter was received.
September 2018	The additional quality data were reviewed and further information was requested.
September 2018	The company's response letter was received.
September 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2018	A desk review for evaluation of compliance for the bioequivalence study for GLP and

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

	GCP was conducted and it met WHO requirements.
18 December 2018	[HA688 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, Indore SEZ
Pharma Zone, Phase-II, Sector-III
Pithampur –454775
Dist. Dhar
Madhya Pradesh
India

Inspection status

The active pharmaceutical ingredient and finished pharmaceutical product manufacturing sites were found to be in compliance with WHO requirements for GMP.

A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP was conducted, and it met WHO requirements.

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