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 [HP025 trade name]* (HP025) to be assessed with the aim of including [HP025 trade name] in the list of prequalified medicinal products for the treatment of hepatitis C infections.

[HP025 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 GCP.
November 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
November 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
January 2019	The applicant's response letter was received.
January 2019	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
December 2018 and February 2019	In between the meetings of the assessment team the quality data were reviewed and further information was requested.
May 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.
July + August 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2019	The applicant's response letter was received.
November 2019	The manufacturer of the APIs was inspected for compliance with WHO requirements for GMP.
January 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2020	The applicant's response letter was received.
February 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
February 2020	Product dossier accepted (quality assurance)

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

27 October 2020	[HP025 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
F- 4 & F-12, 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products