Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2015 an application for [HP001 trade name]* to be assessed with the aim including [HP001 trade name] in the list of prequalified medicinal products for the treatment of hepatitis C.

[HP001 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 for the assessment of the product

March 2013	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
Sept 2014	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Nov 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Dec 2015 Feb 2016	In between the meetings of the assessment team the quality data were reviewed and further information was requested.
April 2016	The company's response letter was received.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2016	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP.
July 2016	The company's response letter was received.
Sept 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2016	The company's response letter was received.
Nov 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2017	The company's response letter was received.
Jan 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2017	The company's response letter was received.
April 2017	In between the meetings of the assessment team the quality data were reviewed and further information was requested.
May 2017	The company's response letter was received.
June 2017	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2017	Product dossier accepted (quality assurance)
20 July 2017	[HP001 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, commitments and inspection status

Manufacturer of the finished product and responsible for batch release:

Mylan Laboratories Limited (FDF Unit-1)
F-4 & F-12, MIDC, Malegaon
Sinnar, Nashik – 422 113
Maharashtra
India

Commitments for Prequalification

None which have an impact on the benefit-risk profile of the medicinal product

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP, GCP and GLP.

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/