Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Limited, Hyderabad, Telangana, India submitted in 2016 an application for [HP002 trade name]* (HP002) to be assessed with the aim of including [HP002 trade name] in the list of prequalified medicinal products for treatment of chronic hepatitis C (CHC) in adults and in adolescents.

[HP002 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 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
April 2016	The quality data were reviewed and further information was requested
April 2016	The applicant's response letter was received.
May 2016	During the meeting of the assessment team the additional s safety and efficacy 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 and GCP.
August 2016	The applicant's response letters were received.
September 2016	During the meeting of the assessment team the additional quality data team the additional safety and efficacy data were reviewed and further information was requested.
January 2017	The applicant's response letters were received.
January 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
February 2017	The manufacturers of one API were inspected for compliance with WHO requirements for GMP.
February 2017	The applicant's response letter was received.
March 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2017	The applicant's response letter was received.
May 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2017	The applicant's response letter was received.

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

September 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2017	The applicant's response letter was received.
November 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November and December 2017	The additional quality data were reviewed and further information was requested.
January 2018	The applicant's response letter was received.
January 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
January 2018	Product dossier accepted (quality assurance)
07 February 2018	[HP002 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

Hetero Labs Limited, Unit-V
TSIIC Formulation SEZ,
Survey No. 439,440,441 & 458
Polepally village, Jadcherla Mandal,
Mahaboob Nagar (Dist) – 509301,
Telangana, 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