STEPS TAKEN FOR PREQUALIFICATION

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Hetero Labs Ltd. submitted in 2017 an application for [HP011 trade name][*] to be assessed with the aim of including [HP011 trade name] in the list of prequalified medicinal products for the treatment of chronic hepatitis C virus infections.

[HP011 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

October 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
December 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
November 2017	During the meeting of the assessment team, the safety and efficacy data were reviewed and further information was requested.
January 2018	The applicant's response letter was received.
January 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2018	During the meeting of the assessment team the quality data were reviewed and further information was requested.
April 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.
June 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.
September 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
December 2018	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2019	A desk review for evaluation of compliance of the manufacturer of one API for GMP was conducted and it met WHO requirements.
March 2019	The applicant's response letter was received.
March 2019	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
May 2019	The applicant's response letter was received.
November 2019	During the meeting of the assessment team, the additional quality data were reviewed and further information was requested.
November 2019	The applicant's response letter was received.
November 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2019	Product dossier accepted (quality assurance)
17 Dec 2019	[HP011 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 (NMRA) responsibility.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:
Hetero Labs Ltd (Unit 5)
Survey No. 439, 440, 441 & 458
TSIIC formulation SEZ
Polepally village
Jadcherla Mandal,
Mahaboob Nagar District
Telangana, 509 301
India

Commitments for Prequalification

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

Inspection status

The manufacturing sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for GCP/GLP since a biowaiver applies.

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/