Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company European Egyptian Pharmaceutical Industries submitted in 2016 an application for [HP003 trade name]* (HP003) to be assessed with the aim of including [HP003 trade name] in the list of prequalified medicinal products for the treatment of chronic hepatitis C infection.

[HP003 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

April 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May and June 2016	During the meeting of the assessment team the quality data were reviewed and further information was requested.
June 2016	The company's response letter was received.
July 2016	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
August 2016	The company's response letter was received.
Sept 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Sept 2016	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
Jan and March 2017	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
May 2017	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
May 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2017	The company's response letter was received.
July 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2017	The company's response letter was received.
Nov 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Feb 2018	The company's response letter was received.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.

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

April 2018	The company'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.
May 2018	The company's response letter was received.
May and Oct 2018	The additional quality data were reviewed and further information was requested.
Nov 2018	The company's response letters were received.
Nov 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2018	The company's response letters were received.
Nov 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
Nov 2018	Product dossier accepted (quality assurance)
18 Dec 2018	[HP003 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

European Egyptian Pharmaceutical Industries

Alexandria-Cairo Desert Road Km 25

Amriya, Alexandria

El Manshia Alex

Egypt

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/medicines/prequalified/finished-pharmaceutical-products