Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Laboratorios León Farma SA submitted in 2016 an application for [RH068 trade name]* (RH068) to be assessed with the aim of including [RH068 trade name] in the list of prequalified medicinal products for contraception for woman.

[RH068 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 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested
October 2016	The quality data were reviewed and further information was requested.
April 2017	The applicant's response letter was received.
June 2017	The additional quality data were reviewed and further information was requested.
May 2018	The applicant's response letter was received.
June 2018	The additional quality data were reviewed and further information was requested.
August 2018	The applicant's response letter was received.
February 2020	The applicant's response letter was received.
April 2020	The additional safety and efficacy data were reviewed and further information was requested.
July 2020	In between the meetings of the assessment team the applicant's response letter was received. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2020	The applicant's response letter was received.
December 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2020	Product dossier accepted (quality assurance).
05 February 2021	[RH068 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 and Inspection status

Manufacturer of the finished product and responsible for batch release

Laboratorios Leon Farma SA
C/La Vallina s/n
Poligono Industrial Navatejera
Villaquilambre
Leon 24008
Spain

Inspection status

Not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

API supported by a CEP. Inspection of the manufacturing site waived based on previous satisfactory inspection by a stringent regulatory authority.

Not inspected for GCP/GLP since a biowaiver applies.

Further information is available at:

https://extranet.who.int/prequal/