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 [RH069 trade name]* (RH069) to be assessed with the aim of including [RH069 trade name] in the list of prequalified medicinal products for contraception for woman.

[RH069 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 letters were received.
May 2017	During the meeting of the assessment team the additional, safety and efficacy data were reviewed and further information was requested.
June 2017	The additional quality data were reviewed and further information was requested.
June 2017	The applicant's response letter was received.
July 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
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.
December 2018	A desk review for evaluation of compliance for the bioequivalence study for GCP met WHO requirements.
September 2020	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met 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	[RH069 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 GCP (Bioequivalence study conducted in a member country of the ICH).

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.

API supported by a CEP. Inspection of the manufacturing site waived based on risk assessment.

Further information is available at:

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