Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Laboratorios Leon Farma SA submitted in 2016 an application for [RH071 trade name]* (RH071) to be assessed with the aim of including [RH071 trade name] in the list of prequalified medicinal products as an oral combined hormonal contraceptive (CHC) agent for women.

[RH071 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.
November 2016	During the meeting of the assessment team 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 efficacy data were reviewed and further information was requested.
June 2017	The applicant's response letter was received.
July 2017	During the meeting of the assessment team the additional quality and the additional efficacy data were reviewed and further information was requested.
April 2018	The applicant's response letters were received.
May 2018	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
June 2018	The additional quality data were reviewed and further information was requested.
July 2018	The applicant's response letter was received.
July 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
August 2018	The applicant's response letter was received.
September and October 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2018	The applicant's response letter was received.

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

November 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 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.
April 2019	The applicant's response letter was received.
January 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2020	The applicant's response letter was received.
February 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
February 2020	Product dossier accepted (quality assurance).
March 2020	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP was conducted and it met WHO requirements
21 April 2020	[RH071 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

Laboratorios Leon Farma SA
La Vallina s/n
Poligono Industrial Navatejera, Villaquilambre
Leon 24193
Spain

Inspection status

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

A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.

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