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 [RH067 trade name]* (RH067) to be assessed with the aim of including [RH067 trade name] in the list of prequalified medicinal products as an oral combined hormonal contraceptive (CHC) agent for women.

[RH067 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 quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2018	A desk review for evaluation of compliance of the manufacturer of the FPP for GMP was conducted and it met WHO requirements.
June 2018	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.
November 2018	The applicant's response letter was received.
November 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
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.
June 2019	The applicant's response letter was received.
July 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2019	A desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.

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

September 2019	The applicant's response letter was received.
September 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2019	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
January 2020	The applicant's response letter was received.
March 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2020	The applicant's response letter was received.
September 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2020	The applicant's response letter was received.
October 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
October 2020	Product dossier accepted (quality assurance)
27 October 2020	[RH067 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

API manufacturers not inspected for GMP. Previous inspections by a stringent regulatory authorities 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