## 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 [RH066 trade name]* (RH066) to be assessed with the aim of including [RH066 trade name] in the list of prequalified medicinal products as an oral combined hormonal contraceptive (CHC) agent for women.

[RH066 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

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| 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.<br>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. |
| May 2018 | During the meeting of the assessment team 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.

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| 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 | [RH066 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 24008

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/