Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Bayer S.A. Av. submitted in 2018 an application for [RH087 trade name]* (RH087) to be assessed with the aim of including [RH087 trade name] in the list of prequalified medicinal products for contraception for women.

[RH087 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

September 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
October 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
November 2018	During the meeting of the assessment team the 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.
June 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.
October 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.
February 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.
May 2020	The applicant's response letter was received.
July 2020	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2020	The applicant's response letter was received.
August 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.
August 2020	The quality data were reviewed and found to comply with the relevant WHO

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

	requirements.
August 2020	Product dossier accepted (quality assurance)
18 August 2020	[RH087 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

Bayer de México S.A. de C.V.
Orizaba, Ojo de Agua S/N
94450 Ixtaczoquitlán, Veracruz
Mexico

Inspection status

Inspection of API manufacturing sites waived based on previous satisfactory inspection by a stringent regulatory authority and availability of CEPs.

The FPP manufacturing site was inspected and found to be in compliance with WHO requirements for GMP.

Not inspected for GCP/GLP, since a biowaiver applies.

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/