Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Bayer AG submitted in 2014 an application for [RH054 trade name]* (RH054) to be assessed with the aim of including [RH054 trade name] in the list of prequalified medicinal products for contraception for women,

[RH054 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

January 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
April 2015	The quality data were reviewed and further information was requested.
August 2016	The applicant's response letter was received.
November 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May 2016	The applicant's response letter was received.
July and September 2017	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
December 2017	The applicant's response letter was received.
February 2018	The additional quality data were reviewed and further information was requested.
April 2018	The applicant's response letter was received.
June 2018	The additional quality data were reviewed and further information was requested.
October 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
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.
January 2019	The applicant's response letter was received.
January 2019	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 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	The applicant's response letter was received.

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

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	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2020	Product dossier accepted (quality assurance)
30 July 2020	[RH054 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. No bioequivalence study was required as [RH054 trade name] is the comparator product.

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/