Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Renata Limited submitted in 2020 an application for [RH093 trade name]* (RH093) to be assessed with the aim of including [RH093 trade name] in the list of prequalified medicinal products for female contraception.

[RH093 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

October 2018	The manufacturer of one API was inspected for compliance with WHO requirements for GMP.
March 2020	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
April 2020	The applicant's response letter was received.
May 2020	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March and May 2020	During the meetings of the assessment team the quality data were reviewed and further information was requested.
September 2020	The applicant's response letter was received.
September and December 2020	The additional quality data were reviewed and further information was requested.
January 2021	The applicant's response letter was received.
January and March 2021	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
April 2021	The applicant's response letter was received.
May 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2021	The applicant's response letter was received.
July 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2021	The applicant's response letter was received.
November 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2022	The applicant's response letter was received.

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

March and April 2022	The additional quality data were reviewed and further information was requested.
June 2022	The applicant's response letter was received.
July 2022	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July and August 2022	The additional quality data were reviewed and further information was requested.
September 2022	The applicant's response letter was received.
September 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2022	The applicant's response letter was received.
November 2022	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2023	The applicant's response letter was received.
March 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2023	The applicant's response letter was received.
May 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2023	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
June 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2023	The applicant's response letters were received.
September 2023	During the meeting of the assessment team the additional quality data and additional safety and efficacy data were reviewed and further information was requested.
October 2023	The applicant's response letter was received
November 2023	In between the meetings of the assessment team the applicant's response letter was received. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November and December 2023	The additional quality data were reviewed and further information was requested.
January 2024	The applicant's response letter was received.
January 2024	The additional quality data were reviewed and further information was requested.
January 2024	The applicant's response letter was received.
January 2024	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2024	The applicant's response letter was received.
January 2024	The quality data were reviewed and found to comply with the relevant WHO requirements.
February 2024	Product dossier accepted (quality assurance)

22 February 2024	[RH093 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

Renata Limited
Rajendrapur Potent Product Facility,
Noyapara, Bhawal Mirzapur,
Rajendrapur,
Gazipur 1700 Bangladesh

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

API manufacturer of levonorgestrel and one API manufacturer ethinylestradiol were not inspected for GMP. Previous inspections by a stringent regulatory authority were acceptable.

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