Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Incepta Pharmaceuticals Limited submitted in 2018 an application for [RH084 trade name][*] (RH084) to be assessed with the aim of including [RH084 trade name] in the list of prequalified medicinal products for contraception in women.

[RH084 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 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2018	During the meeting of the assessment team the safety and efficacy 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 quality data and the additional efficacy data were reviewed and further information was requested.
November 2018	The applicant's response letters were received.
November 2018	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
February 2019	The additional quality data were reviewed and further information was requested.
May 2019	The applicant's response letter was received.
May 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.
August 2019	The assessment team the additional quality data were reviewed and further information was requested.
September 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.
January 2020	The applicant's response letters were received.
January 2020	The quality data were reviewed and found to comply with the relevant WHO requirements.
January 2020	Product dossier accepted (quality assurance)
05 February 2020	[RH084 trade name] was included in the list of prequalified medicinal products.

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Incepta Pharmaceuticals Limited

Unit-1, Injectable Potent Drug (IPD)

Krishnapura, Sahabelishor

Dhamrai, Dhaka

Bangladesh

Inspection status

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

API manufacturer not inspected for GMP. Previous inspections by a stringent regulatory authority showed acceptable outcome

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