Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Incepta Pharmaceuticals Ltd submitted in 2024 an application for [RH106 trade name]* (RH106) to be assessed with the aim of including [RH106 trade name] in the list of prequalified medicinal products for use for long-term contraception in women.
[RH106 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 2024	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
September and November 2024	During the meetings of the assessment team the quality data were reviewed and further information was requested.
November 2024	The applicant's response letter was received.
November 2024	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2025	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
January 2025	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
February 2025	The applicant's response letter was received.
March 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2025	The applicant's response letter was received.
May and June 2025	The additional quality data were reviewed and further information was requested.
July 2025	The applicant's response letter was received.
July and September 2025	During the meetings of the assessment team the additional quality data were reviewed and further information was requested.
September 2025	The applicant's response letter was received.
September 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2025	The applicant's response letter was received.
September 2025	The quality data were reviewed and found to comply with the relevant WHO requirements.
September 2025	Product dossier accepted (quality assurance)
01 October 2025	[RH106 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 Ltd
Unit-10, 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.

Inspection of API manufacturer waived based on risk assessment

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