Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company HLL Lifecare Limited submitted in 2016 an application for [RH065 trade name]* (RH065) to be assessed with the aim of including [RH065 trade name] in the list of prequalified medicinal products for emergency contraception for women.

[RH065 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 2016	During the meeting of the assessment team the safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July/September 2016	During the meeting of the assessment team the quality data were reviewed and further information was requested.
December 2016	The applicant's response letter was received.
January 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2017	The applicant's response letter was received.
May 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2017	The applicant's response letter was received.
July 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2017	The applicant's response letter was received.
September 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
December 2017	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
March 2018	The applicant's response letter was received.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2018	The applicant's response letter was received.
April 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.

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

April 2018	Product dossier accepted (quality assurance)
23 April 2018	[RH065 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

HLL Lifecare Limited (A Government of India Enterprise)
Unipill Block,
Kanagala,
Belagavi District,
Karnataka-591225
India.

Inspection status

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

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