Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Famy Care Limited Ltd submitted in 2013, an application for [RH031 trade name]* (RH031) to be assessed with the aim of including [RH031 trade name] in the list of prequalified medicinal products for emergency contraception.

[RH031 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

March 2012	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
April 2012	The company's response letter was received.
May 2012	During the meeting of the assessment team the quality data and the additional efficacy data were reviewed and further information was requested.
May 2012	The company's response letters were received.
July2012	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Sept 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
October 2012	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
May 2013	The company's response letter was received.
May 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2013	The company's response letters were received.
July 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Aug 2013	The quality data were reviewed and found to comply with the relevant WHO requirements.
Oct 2013	Product dossier accepted (quality assurance)
21 Oct 2013	[RH031 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, commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Famy Care Limited
Plot No. 20 & 21, Pharmez
Phamaceutical Special Economic Zone (SEZ)
Sarkhej, Near Matoda, Village, Ahmedabad
India

Commitments for Prequalification

None

Inspection status

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

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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products