Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Famy Care Ltd submitted in 2012 an application for [RH032 trade name][*] (RH032) to be jointly assessed with the aim of including [RH032 trade name] in the list of prequalified pharmaceutical products for emergency contraception.

[RH032 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

May 2012	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
Aug 2012	The company's response letters were received.
Sept 2012	During the meeting of the assessment team the additional quality and efficacy data were reviewed and further information was requested.
Sept 2012	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Oct 2012	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
Nov 2012	The company's response letter was received.
Nov 2012	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2012	The company's response letters were received.
Jan 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements
Feb 2013	The company's response letter was received.
March 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
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.
June 2013	The company's response letter was received. The quality data were reviewed and found to comply with the relevant WHO

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

	requirements
June 2013	Product dossier accepted (quality assurance)
14 June 2013	[RH032 trade name] was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Famy Care Ltd
Plot No. 20 & 21, Pharmez
Pharmaceutical 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 site not inspected for GMP, due to previous inspections by a stringent regulatory authority which 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