I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Famy Care Ltd submitted in 2008 an application for for [RH013 trade name]* (RH013) to be assessed with the aim of including [RH013 trade name] in the list of prequalified medicinal products for contraception for women.

[RH013 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

Nov 2008 / March 2009	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Oct 2008	The company's response letter was received.
May 2009	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
July 2009	During the meeting of the assessment team the efficacy data were reviewed and further information was requested.
Sept 2009	The company's response letter was received.
Sept 2009	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Dec 2009	The company's response letters were received.
Jan 2010	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Jan 2010	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2010	The company's response letter was received.
March 2010	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
April 2010	In between the meetings of the assessment team a company's response letter was received. The additional quality data were reviewed and further information was requested.
April 2010	The company's response letter was received.
May 2010	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2010	The company's response letter was received.
July 2010	The quality data were reviewed and found to comply with the relevant WHO requirements.
Sept 2011	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
13 Aug 2010	Product dossier accepted (quality assurance).
29 Sept 2011	[RH013 trade name] was included in the list of prequalified medicinal products.

[1]Formerly known as Famy Care Ltd at time of prequalification.

* 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 Ltd. Unit II
1608/1609
G.I.D.C, Sarigam
396155 Valsad
Gujarat, India

Commitments for Prequalification

None which has an impact on the benefit-risk profile of the medicinal product.

Inspection status

API manufacturers not inspected for GMP, as these are innovator sites located within a Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) country.

The FPP sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for GLP /GCP. Previous site inspections by WHO showed acceptable outcome.

2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:

http://www.who.int/prequal