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

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¹Formerly 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