I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Famy Care Ltd. submitted in 2013 an application for Zinnia F* (RH038) to be assessed with the aim of including Zinnia F in the list of prequalified medicinal products for contraception for women.

Zinnia F 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. The countries of origin of the assessors involved with Zinnia F were Canada, China, Germany, Kenya, Netherlands, South Africa, Spain, Switzerland and Uganda.

Licensing status:
Zinnia F has been licensed / registered in the following countries:

Country	Marketing Authorization Number
Georgia	R-014462
Uzbekistan	Б-250-95 № 40514
Ecuador	852-MEE-0315
Malawi	PMPB/PL151/13
Zambia	211/013
Madagascar	28.1.1.259
Tanzania	TZ 14 H 0149
Rwanda	20/1232/DGCS/PH/2014
Uganda	8818/18/14
Zimbabwe	2014.21.2.1/4923
DR Congo	MS. 1253/10/01/0196/2014.
Ghana	FDB/SD.143-6652
Nigeria	B4-1145
Afghanistan	639733
Cambodia	CAM No.613 IP-13
Lao PDR	09I3880/13
Myanmar	1909AA8051
Nepal	6624
Honduras	M - 20694

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

2. Steps taken in the evaluation of the product

March 2013	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Sept 2013	The company's response letter was received.
Sept 2013	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Oct 2013	The company's response letter was received.
Oct 2013	The additional quality data were reviewed and found to comply with the relevant WHO requirements.
Oct 2013	Product dossier accepted (quality assurance)
Nov 2013	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2014	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
11 March 2014	Zinnia F 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:

Active tablets
Famy Care Limited, Unit II
Plot No. 1608-1609, G. I. D.C.
Sarigam, District Valsad
Gujarat, India.396155

Hormone inactive tablets
Famy Care Limited
Plot No. 20 & 21, Pharmez
Pharmaceutical Special Economic Zone (SEZ)
Sarkhej, Near Matoda, Village
Ahmedabad, 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