I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2015 an application for FAMY-POP* (RH057) to be assessed with the aim of including FAMY-POP in the list of prequalified medicinal products for contraception for woman.

FAMY-POP 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 FAMY-POP were Canada, Ethiopia, Germany, Kenya, South Africa, Spain, Switzerland, Uganda and Zimbabwe.

Licensing status:
FAMY-POP has been licensed / registered in the following countries: N/A

2. Steps taken in the evaluation of the product

Oct 2012	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP.
May 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Sept 2015	During the meeting of the assessment team the quality data were reviewed and further information was requested.
Dec 2015	The company's response letters were received.
Jan 2016	During the meeting of the assessment team the additional quality and the additional efficacy data were reviewed and further information was requested.
Feb 2016	The company's response letter was received.
March 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March 2016	The company's response letter was received.
March2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2016	In between the meetings of the assessment team the company's response letter was received. The additional quality data were reviewed and further information was requested.
April 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2016	The company's response letter was received.
July 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2016	Product dossier accepted (quality assurance)
15 Aug 2016	FAMY-POP 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. Throughout this WHOPAR the proprietary name is given as an example only.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Jai Pharma Limited
Plot No. 20/21, Pharmez
The Pharmaceutical Special Economic Zone
Sarkhej - Bavla National Highway No-8A, Nr. Village Matoda
Taluka-Sanand
Dist-Ahmedabad 382 213
Gujarat
India

Commitments for Prequalification

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

Inspection status

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

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/prequal