I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2017 an application for [RH074 trade name][1] (RH074) to be assessed with the aim of including [RH074 trade name] in the list of prequalified medicinal products for contraception in women.

[RH074 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.

Licensing status:
[RH074 trade name] has been licensed / registered in the USA (ANDA 210227).

2. Steps taken in the evaluation of the product

May 2017	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
May and September 2017	During the meeting of the assessment team the quality data were reviewed and further information was requested.
July 2017	The company's response letter was received.
Nov 2017	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2018	The company's response letter was received.
February 2018	The additional quality data were reviewed and further information was requested.
April 2018	The company's response letter was received.
June 2018	The additional quality data were reviewed and further information was requested.
July 2018	The company's response letter was received.
July and October 2018	The additional quality data were reviewed and further information was requested.
October 2018	The company's response letter was received.
October 2018	The quality data were reviewed and found to comply with the relevant WHO requirements.
December 2017	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
September 2018	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP.
October 2018	Product dossier accepted (quality assurance)
31 October 2018	[RH074 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:

Mylan Laboratories Limited
Plot No. 20 & 21,
Pharmaceutical Special Economic Zone
Sarkhej – Bavla National Highway No. 8-A
Matoda, Tal- Sanand
Ahmedabad-382213, India

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

Commitments for Prequalification

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

Inspection status

API and FPP manufacturers were not inspected for GMP. Previous inspections by stringent regulatory authorities showed acceptable outcome.

The site inspected was found to be in compliance with WHO requirements for GCP/GLP.

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/