Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Limited submitted in 2013 an application for [RH046 trade name]* (RH046) to be assessed with the aim of including [RH046 trade name] in the list of prequalified medicinal products for contraception for women within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.

[RH046 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

May 2012	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
September 2013	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
October 2013	The company's response letter was received.
November 2013	During the meeting of the assessment team the additional efficacy and the quality data were reviewed and further information was requested.
20 November 201	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
July 2014	The company's response letters were received.
July 2014	During the meeting of the assessment team the additional efficacy and quality data were reviewed and further information was requested.
August + Septemb 2014	The company's response letters were received.
September 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
October 2014	The company's response letter was received.
November 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2015	The company's response letter was received.
January 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2015	The company's response letter was received.
March 2015	The quality data were reviewed and found to comply with the relevant WHO requirements.
July 2015	Product dossier accepted (quality assurance)
09 July 2015	[RH046 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

Cipla Limited
Unit VIII, Goa

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

M/s Cipla Ltd, L-147 to L-147-1
Verna Industrial estate, Verna Goa
India

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP and GLP.

Not inspected for GCP. Previous inspections by a stringent regulatory authority showed acceptable outcome.

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/medicines/prequalified/finished-pharmaceutical-products