Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd submitted in 2013 an application for [RH040 trade name] * (RH040) to be jointly assessed by WHO/EAC with the aim of facilitating the national registration in the EAC countries of [RH040 trade name]once jointly accepted and included in the list of prequalified pharmaceutical products for emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.

[RH040 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.
May 2013	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
June 2013	The quality data were reviewed and further information was requested.
July 2013	The company's response letter was received.
July 2013	During the meeting of the assessment team the additional 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 additional quality data were reviewed and further information was requested.
Nov 2013	The company's response letter was received.
Nov 2013	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Nov 2013	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Jan 2014	The company's response letters were received.
Jan 2014	During the meeting of the assessment team the additional quality data and safety and efficacy data were reviewed and further information was requested.
March 2014	After receiving the company's response letter the safety and efficacy data and quality data were reviewed and found to comply with the relevant WHO requirements.
March 2014	Product dossier accepted (quality assurance)
08 April 2014	[RH040 trade name] was included in the list of prequalified medicinal products and accepted for national registration in the member states of the EAC.

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

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Cipla Limited†
Unit VIII, Goa
m/s Cipla Ltd, L-147 to L-147-1
Verna Industrial estate,
Verna, Goa 403 722
India

Inspection status

The sites inspected were found to be compliant with WHO requirements for GMP and GLP. Not inspected for GCP, due to location in SRA (USFDA) jurisdiction.

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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products

† Manufacturing site at time of prequalification. For updated address of manufacturing site see patient information leaflet (part3 of this WHOPAR).