Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Cipla Ltd submitted in 2013 an application for [RH039 trade name][*] (RH039) to be jointly assessed by WHO/EAC with the aim of facilitating the national registration in the EAC countries and inclusion of [RH039 trade name] in the list of prequalified medicinal products indicated for induction of labour, prevention of postpartum haemorrhage, induction of abortion (alone in combination with mifepristone or letrozole) and management of incomplete abortion or missed abortion & intrauterine fetal death (alone or in combination with mifepristone).

[RH039 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

April 2013	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	In between the meetings of the assessment team, the quality data were reviewed and further information was requested.
June + July 2013	The company's response letters were received.
July 2013	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.
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 manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Nov 2013	After the company's response letter was received and during the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2014	The company's response letter was received.
Jan 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2014	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
March 2014	After receiving the company's response letter, the quality data were reviewed and found to comply with the relevant WHO requirements.
March 2014	Product dossier accepted (quality assurance)
08 April 2014	[RH039 trade name] 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.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Cipla Limited
L-147 to L-147-1,
L-147-3 to L-138
Unit VIII, Verna Industrial Estate,
Goa 403722, India

Inspection status

The sites inspected were found to be compliant 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products