Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Acme Formulation Pvt Ltd submitted in 2015 an application for [RH056 trade name]* (RH056) to be assessed with the aim of including [RH056 trade name] in the list of prequalified medicinal products for the prevention of postpartum haemorrhage when oxytocin is not available, for induction of labour, for incomplete abortion as well as spontaneous and induced abortion (preferably with mifepristone).

[RH056 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

July 2014	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
March 2015	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
March 2015 June 2015	The quality data were reviewed and further information was requested.
April 2015	The company's response letter was received.
April 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
July 2015	The company's response letter was received.
August 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
October 2015	The company's response letter was received.
November 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
January 2016	The company's response letter was received.
Jan 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2016	The company's response letter was received.
March 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
March 2016	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GCP.
April 2016	Product dossier accepted (quality assurance)
27 April 2016	[RH056 trade name] was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

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

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release

Acme Formulation Pvt. Limited (Hormone Block)
Ropar Road, Nalagarh
Dist. Solan
Himachal Pradesh-174101
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/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