Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company China Resources Zizhu Pharmaceutical Co., Ltd submitted in 2013 an application for [RH048 trade name]* (RH048) to be assessed with the aim of including [RH048 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).

[RH048 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

Nov 2013	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Dec 2013	The 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 GLP and GCP.
April 2014	The company's response letter was received.
May 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2014	The company's response letter was received.
Sept 2014	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Jan 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2015	The company's response letter was received.
July 2015	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
Sept 2015	The company's response letter was received.
Sept 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2015	The company's response letter was received.
Oct 2015	The additional quality data were reviewed and further information was requested.
April 2016	The company's response letter was received.
May 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Sept 2016	The company's response letter was received.
Sept 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
Oct 2016	The company's response letter was received.
Oct 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
Nov 2016	Product dossier accepted (quality assurance)
22 Nov 2016	[RH048 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

China Resources Zizhu Pharmaceutical Co., Ltd.
No. 27, Chaoyang North Road
Chaoyang District, Beijing 100024
P. R. China

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP, GLP and GCP.

API manufacturer not inspected for GMP. 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/pqweb/medicines/prequalified-lists/finished-pharmaceutical-products