Steps before prequalification

I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company China Resources Zizhu Pharmaceutical Co Ltd submitted in 2014 an application for [RH052 trade name][*]: (RH052) to be assessed with the aim of including [RH052 trade name] in the list of prequalified medicinal products for medical termination of developing intra- uterine pregnancy, softening and dilatation of the cervix uteri prior to surgical termination of pregnancy during the first trimester and preparation for the action of prostaglandin analogues in the termination of pregnancy for medical reasons.

[RH052 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

September 2014	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
November 2014	During the meeting of the assessment team the quality data were reviewed and further information was requested.
March 2015	The company's response letter was received.
March 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
June 2015	The company's response letter was received.
July 2015	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
August 2015	The company's response letter was received.
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.
April 2015	The company's response letter was received.
May 2015	The quality data were reviewed and found to comply with the relevant WHO requirements.
Oct 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
January 2016	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
June 2016	Product dossier accepted (quality assurance)
15 August 2016	[RH052 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/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/prequal/medicines/prequalified/finished-pharmaceutical-products