Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company China Resources Zizhu Pharmaceutical Co Ltd submitted in 2018 an application for [RH089 trade name][*] (RH089) to be assessed with the aim of including [RH089 trade name] in the list of prequalified medicinal products for medical management of induced abortion.

[RH089 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

Oct 2018	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
Oct 2018	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Nov 2018	During the meeting of the assessment team the safety and efficacy data were reviewed and further information was requested.
Dec 2018	The applicant's response letter was received.
Jan 2019	During the meeting of the assessment team the additional efficacy data and the quality data were reviewed and further information was requested.
Feb 2019	The applicant's response letters were received.
Mar 2019	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.
Apr + May 2019	The applicant's response letters were received.
Jul 2019	The sites relevant for the bioequivalence study were inspected for compliance with WHO requirements for GLP and GCP (desk review).
Aug 2019	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
Oct 2019	The additional quality data were reviewed and further information was requested.
Oct 2019	The applicant's response letter was received.
Oct 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
Nov 2019	Product dossier accepted (quality assurance)
19 Nov 2019	[RH089 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

Inspection status

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

A desk review for evaluation of compliance of the misoprostol API manufacturer for GMP met WHO requirements.

A previous inspection by a stringent regulatory authority and desk review for evaluation of compliance for the bioequivalence study for GLP and GCP met WHO requirements.

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