# 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 Mifepristone 200mg Tablets[1] (RH052) to be assessed with the aim of including Mifepristone 200mg Tablets 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.

Mifepristone 200mg Tablets 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. The countries of origin of the assessors involved with Mifepristone 200mg Tablets were Canada, Germany, Ghana, Kenya, the Netherlands, South Africa and Switzerland.

**Licensing status:**
Mifepristone 200mg Tablets has not been licensed / registered in any other country.

## 2. Steps taken in the evaluation of the product

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| Sept 2014 | The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements. |
| Nov 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. |
| Aug 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. |
| Nov 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. |
| Jan 2016 | The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. |
| June 2016 | Product dossier accepted (quality assurance) |
| 15 Aug 2016 | Mifepristone 200mg Tablets was included in the list of prequalified medicinal products. |

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

# II GENERAL CONDITIONS FOR THE PREQUALIFICATION

## 1. Manufacturer, Commitments 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

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/prequal/