WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH089 trade name]*

Mifepristone + Misoprostol 200 mg/200 µg tablets

[RH089 trade name], manufactured at China Resources Zizhu Pharmaceutical Co. Ltd, Chaoyang District, Beijing, P. R. China, was included in the WHO list of prequalified medicinal products for the treatment of reproductive health conditions in women on 19 November 2019.

[RH089 trade name] is indicated for induction of abortion, management of missed abortion and intrauterine fetal death. Detailed information on the use of this product is described in the summary of product characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredients (APIs) of [RH089 trade name] are the antiprogestogen compound, mifepristone and the prostaglandin substance, misoprostol.

The efficacy and safety of mifepristone and misoprostol are well established based on extensive clinical experience in the treatment of induction of abortion, management of missed abortion and intrauterine fetal death.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of mifepristone and misoprostol in reproductive health, the team of assessors advised that [RH089 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH089 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [RH089 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	19 Nov 2019	listed
Quality	31 Oct 2019	MR
Bioequivalence	6 Nov 2019	MR
Safety and efficacy	Not applicable	Not applicable
GMP (re-)inspection		
API	19 Oct 2018	MR
API	16 Aug 2019	MR
FPP	26 Oct 2018	MR
GCP/GLP (re-)inspection	2 July 2019	MR*

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GLP: good laboratory practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification

The table represents the status of relevant completed activities only.

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