WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH028 trade name]*

Levonorgestrel 75 mg Sub-dermal Implant

[RH028 trade name], manufactured at Shanghai Dahua Pharmaceutical Co. Ltd., Shanghai, China, was included in the WHO list of prequalified medicinal products for contraception for women on 30 June 2017.

[RH028 trade name] is indicated for contraception. 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 ingredient of [RH028 trade name] is levonorgestrel.
The efficacy and safety of levonorgestrel are well established based on extensive clinical experience in contraception for women.
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 levonorgestrel in contraception, the team of assessors advised that [RH028 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH028 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH028 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	30 June 2017	listed
Quality	21 March 2017	MR
Bioequivalence	05 April 2017	MR
Safety, efficacy	22 March 2017	MR
GMP (re-)inspection		
API	16 October 2015	MR
FPP	08 June 2015	MR
GCP/GLP (re-)inspection	22 December 2016	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.