WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH087 trade name]*

Estradiol valerate /Norethisterone enantate 5mg/50mg/mL Solution for Injection

[RH087 trade name], manufactured at Bayer de México S.A de C.V, Ixtaczoquitlán, Veracruz, Mexico was included in the WHO list of prequalified medicinal products for hormonal contraception for women on 18 August 2020.

[RH087 trade name] is indicated for hormonal contraception for women. 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 of [RH087 trade name] are estradiol valerate and norethisterone enantate.

The efficacy and safety of estradiol valerate and norethisterone enantate are well established based on extensive clinical experience in hormonal 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 estradiol valerate and norethisterone enantate for hormonal contraception for women, the team of assessors advised that [RH087 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH087 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [RH087 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	18 August 2020	Listed
Quality	07 August 2020	MR
Bioequivalence	12 August 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	NA	NA
FPP	12 October 2018	MR
GCP/GLP (re-)inspection	NA	NA

MR: meets requirements

NA: not applicable, not available

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.