WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA176 trade name]*

Primaquine (as phosphate) 15 mg tablets

[MA176 trade name], manufactured at Macleods Pharmaceuticals Limited, Baddi, Himachal Pradesh., India, was included in the WHO list of prequalified medicinal products for the treatment of malaria on 22 December 2023.

[MA176 trade name] is indicated in combination with either artemisinin-based combination therapy (ACT) or chloroquine for the radical cure of *Plasmodium vivax* and *Plasmodium ovale* malaria. It is also used to reduce the transmissibility of *Plasmodium falciparum* infections in low-transmission areas. 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 [MA176 trade name] is primaquine phosphate

The efficacy and safety of primaquine are well established based on extensive clinical experience in the treatment of malaria.

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 primaquine in malaria, the team of assessors advised that [MA176 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [MA176 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [MA176 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	22 December 2023	listed
Pharmaceutical quality	17 December 2023	MR
Bioequivalence	18 December 2023	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	28 June 2022	MR
FPP	11 November 2022	MR
GCP/GLP (re-)inspection	NA	NA

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

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