WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[MA104 trade name]*

Artesunate/amodiaquine (as hydrochloride) 100 mg/270 mg tablets

[MA104 trade name], manufactured at Cipla Limited, Patalganga, India was jointly accepted by WHO/EAC (East African Community) and included in the WHO list of prequalified medicinal products for the purpose of facilitating the national registration of the product by the countries of EAC for the treatment of malaria on 8 April 2014.

[MA104 trade name] is a so called artemisinin-based combination therapy (ACT) for the treatment of uncomplicated cases of malaria due to *Plasmodium falciparum* strains which are susceptible to amodiaquine as well as to artesunate.

The active pharmaceutical ingredients (APIs) of [MA104 trade name] are the 4-aminoquinoline amodiaquine and the artemisinin derivative artesunate. Each of these APIs, marketed as the therapeutic component of single products, is well-established and documented for the treatment of malaria, especially in combination with each other and with other products.

Efficacy and safety of amodiaquine and artesunate in uncomplicated *P. falciparum* malaria have been demonstrated in comparative clinical trials in West and Central Africa and in Madagascar and the efficacy and safety profile of artesunate and amodiaquine is sufficiently established based on 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 artemisinin-based combination therapy in malaria, the team of WHO/EAC assessors jointly accepted [MA104 trade name] for inclusion in the list of prequalified medicinal products for the purpose of facilitating national registration of the product in the member states of the EAC.

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

Summary of prequalification status for [MA104 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	08 April 2014	listed
Dossier Evaluation (Quality assurance)		
Quality	25 March 2014	MR
Bioequivalence	28 March 2014	MR
Safety, efficacy	NA	NA
Inspection Status		
GMP (re-)inspection		
API	20 Jan 2011	MR
API	14 Feb 2014	MR
FPP	21 Feb 2014	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

The table represents the status of relevant completed activities only.

Requalification	3 June 2020