

# **APPLICATION FOR THE INCLUSION OF ARTESUNATE - MEFLOQUINE (Artequin<sup>®</sup> Paediatric Stickpack) IN THE WHO ESSENTIAL DRUG LIST**

## **Comments from GMP/CMR**

The Global Malaria Programme WHO supports the availability of formulations of antimalarial medicines, and in particular artemisinin based combination therapies (ACTs) suitable for paediatric use, and continues to encourage manufacturers to invest in the manufacture of suitable fixed dose paediatric formulations. However, the GMP Department cannot support this particular application for the following major reason:

- Artequin<sup>®</sup> Paediatric Stickpack is presented as a line-extension of the already existing Artequin<sup>®</sup> co-blistered oral dosage form of artesunate and mefloquine. However, artequin<sup>®</sup> Paediatric Stickpack being a fixed dose combination is an entirely new formulation, and should be considered as such.
- The evidence provided in this submission on artequin<sup>®</sup> Paediatric Stickpack is based on a single study from Gabon (AM-P 001-2005/SPC25-21), with only a total of 39 children aged 1 to 13 years exposed to this formulation. All other evidence on safety and efficacy is based on the loose co-blistered formulation administered simultaneously (AM 001-2001, AM 002-2001). There is insufficient evidence provided to the GMP Department, nor is there evidence available in the public domain on the safety and efficacy of this fixed dose formulation and dosage regimen recommended in this submission.