MEMORANDUM

From:	Dr Peter Olumese GMP/CMR	**To:**	Dr Suzanne Hill PSM/PAR	**Date:**	15 February 2007
Our ref:	M50/370/20	**Attention:**			
Your ref:		**Through:**			
Originator:	PO/elk	**Subject:**	**APPLICATION FOR THE INCLUSION OF ARTEMETHER-LUMEFANTRINE PAEDIATRIC POWDER FOR SUSPENSION (Co-Artesiane□) 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 artesminin based combination therapies (ACTs) suitable for paediatric use, and continues to encourage manufacturers to invest in the manufacture of suitable paediatric formulations. However, the GMP Department cannot support this particular application for the following major reason:

- The doses per age groups, and the dosage regimen (single daily dose) recommended in the submitted dossier is at variance with the current recommended WHO schedules (WHO Guidelines for the Treatment of Malaria, 2006). There is no evidence provided to the GMP Department nor is there evidence available in the public domain on the safety and efficacy of the dosages and regimen recommended in this submission.

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