



Dr. Suzanne Hill, c/o WHO,
The Secretary of the Expert Consultation on
Essential Medicines for Children
Department of Medicines Policy and Standards
20, Avenue Appia
1222 Geneva 27

Aesch, 31.5.07

Subject: Clarification on artesunate rectal application (referred to by Dr. P. Olumese, GMP / WHO)

Dear Dr. Hill,

Referring to the above mentioned application, we herewith like to clarify that the rectal application forms (50 and 200 mg) mentioned by Dr. Olumese are Mepha patent protected thermostable rectal formulations. These formulations are also trademark protected, i.e. Plasmotrim™ Rectocaps™.

We are happy to see that these important products will be discussed to be added to the essential list, especially also having in mind that nearly all studies mentioned by Dr. Olumese have been conducted with Plasmotrim™ Rectocaps™. Even Dr. John Mc Ewen, Member of the WHO Expert advisory Panel, writes in his report "...the Plasmotrim™ Rectocaps™ are in effect an innovator product".

The formulations and dosages applied for should therefore be referred to as manufactured and marketed by Mepha Ltd., Aesch / Switzerland.

We kindly ask you to confirm this important clarification.

With kind regards,

Mepha Ltd.

Dieter Meppiel
International Product Manager Malaria

Dr. Déborah Schiestel
International Regulatory Affairs Manager