The Secretary of the WHO Expert Committee on the Selection and Use of Essential Medicines
Department of Medicines Policy and Standards
World Health Organization (WHO)
20 avenue Appia
1211- Genève 27

8 November 2010

To whom it may concern,

MMV would like to endorse sigma-tau’s application for the inclusion of dihydroartemisinin piperazine phosphate in the WHO Model List of Essential Medicines.

Eurartesim™, the fixed-dose combination version of this medicine that sigma-tau has co-developed with support from MMV, was submitted to the European Medicines Agency for regulatory approval in July 2009, and is expected to complete its regulatory review with approval in Q1 2011. The product dossier will then be immediately submitted to WHO Prequalification to be considered for inclusion in the list of prequalified medicines for treating malaria.

As a promising cost-effective therapy for the treatment of uncomplicated P. falciparum, dihydroartemisinin piperazine phosphate presents an interesting challenge for the global health community. On the one hand, widespread clinical evidence demonstrating the drug’s safety and efficacy has been strong enough for the WHO to have added this therapy to its 2010 version of its Guidelines for the Treatment of Malaria (a “strong recommendation” with “high quality evidence.”) On the other hand, no currently marketed version of this product has satisfied GMP requirements nor WHO prequalification standards. We believe this situation will be remedied within a matter of months and that patients will finally be able to access an internationally acceptable quality version of the product.

As such, we would encourage the Expert Committee on Essential Medicines to review the clinical data demonstrating this drug’s performance, to digest the same body of evidence reviewed by WHO’s Technical Guidelines Development Group, and to consider the potential public health demand for this product in malaria-impacted countries in Africa and Asia. (The example of Cambodia’s dilemma is particularly compelling: the government will have waited for months for a quality version of this product to be made available – and immediately post approval, to become the new first line treatment there replacing co-blistered AS+MQ1.)

We urge the WHO’s Expert Committee on the Selection and Use of Essential Medicines to consider dihydroartemisinin piperazine phosphate for a timely adoption into the WHO Model List of Essential Medicines.

Yours sincerely,

Dr. Dennis Schmatz
President and CEO, Medicines for Malaria Venture (MMV)

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1 Per PSI Cambodia’s malaria technical officer and WHO’s malaria scientist in Cambodia, WHO facilitated a national guideline revision meeting in April 2010 at which it was decided that as soon as DHA-PQP became prequalified, the drug would become the national first line treatment replacing co-blistered AS+MQ.