The European Agency for the Evaluation of Medicinal Products
Pre-authorisation Evaluation of Medicines for Human Use

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COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

PUBLIC SUMMARY OF NEGATIVE OPINION FOR ORPHAN DESIGNATION OF chlorproguanil hydrochloride and dapsone for the treatment of acute uncomplicated *Plasmodium falciparum* malaria

On 22 May 2002 the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on orphan designation of the combination of chlorproguanil hydrochloride and dapsone (Lapdap) in treatment of acute uncomplicated *Plasmodium falciparum* malaria. A negative decision was granted by the European Commission on 26 July 2002.

The sponsor applied for orphan designation on the basis of assumption of potential significant benefit despite currently available methods of treatment, as well as on the severity and the rarity of the condition.

The negative opinion is based on the following element:

- Satisfactory methods of treatment of the condition were authorised in the Community, and justification has not been provided that the combination of chlorproguanil hydrochloride and dapsone may be of significant benefit to those affected by the condition in comparison to currently available therapies.

  Lapdap is primarily proposed for treatment of patients in malaria endemic regions of Africa, and does not meet the criteria for orphan designation in Europe.

Requests for designation as orphan medicinal products are made for investigational products. Absence of orphan designation does not preclude the development of this product, in particular through clinical trials, and subsequently the possibility of obtaining a marketing authorisation if quality, safety and efficacy are demonstrated.

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