Expert Committee on the Selection and Use of Essential Medicines

April 8-12, 2013

Expert peer review on application for adding Artesunate and Mefloquine (ASMQ) FDC

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes No √ (if no, please provide reference and information)

   Clinical studies to support the efficacy of ASMQ fixed dose combination has been considered not necessary as the extensive use of both medicines in non-fixed combinations or as co-blister formulations supports the efficacy of these.

   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      Data on efficacy is available for AS+MQ non-fixed drug combinations and show that the drugs are very efficacious with a cure rate of up to 100%.

   c. Please provide any additional relevant information with reference

2. Assessment of safety
   a. Have all relevant studies on safety been included
      Yes No √ (if no, please provide reference and information)

   The studies included are those that have been concluded. There are studies that are ongoing still.

   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      The completed clinical safety studies on ASMQ fixed dose combination showed mild to moderate treatment emergent adverse effects involving the gastrointestinal tract (vomiting, diarrhea), blood and lymphatic system disorders (anemia and eosionphilia).

   c. Please provide any additional relevant information with reference

3. Assessment of cost and availability
   a. Have all relevant data on cost and availability provided
      Yes No √ (if no, please provide reference and information)

   b. Summarize the data on cost and cost effectiveness, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
No data on cost or cost effectiveness of AMSQ fixed dose combination are yet available.

c. Please provide any additional relevant information with reference

d. Is the product available in several low and middle income countries?

It is not available as a fixed drug combination.

4. Assessment of public health need

a. Please provide the public health need for this product (1-2 sentences)

Artesunate and Mefloquine are already regarded by the WHO as essential medicines for the treatment of malaria but a fixed drug combination of both drugs will improve patient compliance as there are less tablets to take, once a day for three days. With improved compliance resistance to the drugs will be minimized.

b. Do guidelines (especially WHO guidelines) recommend this product? If yes, which ones? List 1 or 2 international preferable


5. Are there special requirements for use or training needed for safe/effective use?
If yes, please provide details in 1-2 sentences

Yes ✓

All patients suspected to have malaria should have a diagnostic test before treatment is started. If parasitological diagnosis is not accessible antimalarial treatment should be considered on clinical suspicion.

6. Is the proposed product registered by a stringent regulatory authority?

Yes ✓  No

7. Any other comments?

No

8. What is your recommendation to the committee (please provide the rationale)

AS-MQ the fixed drug combination from CIPLA is not available in Kenya. No recommendations can be made at this point until the ongoing ASMQ FDC clinical studies in Kenya are concluded.