19th Expert Committee on the Selection and Use of Essential Medicines
April 8-12; 2013

Expert peer review on application for “Addition of LTRA (Montelukast) to EMLc”

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes
   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      N/A. There is not any Anti Leukotrienes on the List.
   c. Please provide any additional relevant information with reference

2. Assessment of safety
   a. Have all relevant studies on safety been included
      Yes
   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      N/A. There is not any Anti Leukotrienes on the List.
   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
      No
   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)
      N/A. There is not any Anti Leukotrienes on the List.
   c. Please provide any additional relevant information with reference
   d. Is the product available in several low and middle income countries?
      No

4. Assessment of public health need
   b. Do guidelines (especially WHO guidelines) recommend this product?
      No, in WHO guidelines.
5. Are there special requirements for use or training needed for safe/effective use?
   No.

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

7. Any other comments
   1. The application proposed to add LTRA medicines (Montelukast) to EMLc for treating allergic rhinitis (AR)
   2. RA is not usually harmful but it can be irritating and affect patients’ quality of life.
   3. LTRA medicines are not available in many low and middle income countries.

8. What is your recommendation to the committee (please provide the rationale)
   1. RA is not a priority disease either for many low and middle income countries or for WHO.
   2. RA could be managed with many other medicines including antihistamines and decongestants. There is already another application submitted to the committee for updating antihistamines in EML and EMLc
   3. Final recommendation: “Do not add LTRA medicines (Montelukast) to the List”.