19th Expert Committee on The Selection and Use of Essential Medicines

April 8-12 2013

Expert peer review on application to add ketotifen under ophthalmological preparations

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

   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      Ketotifen is efficacious in seasonal allergic conjunctivitis when compared to placebo. It is as effective as some of the other antihistamines (topical application).

   c. Please provide any additional relevant information with reference

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

   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      There are no topical ocular antihistamines that have been included in the EML.

   c. Please provide any additional relevant information with reference

3. Assessment of cost and availability
   a. Have all relevant data on cost been provided
      Yes.

   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)
      Generic ketotifen is available. The cost of a single vial in the United States of America is approximately 43 USD; in India a single vial is approximately one USD.

   c. Please provide any additional relevant information with reference

   d. Is the product available in several low and middle income countries?
      Yes
4. **Assessment of public health need**  
a. Please provide the public health need for this product (1-2 sentences)

Seasonal allergic conjunctivitis is quite common. The symptoms are generally quite mild and not very distressing. It is estimated that 15-20% of people may suffer from this. There is no significant public health need for this product.

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

No. Ketotifen is not recommended by any WHO guidelines.

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

No.

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

7. **Any other comments**

Under section 15 of the review (proposed text for the WHO Model Formulary) the brand name Zaditor has been mentioned in all of the text. This should not be done and the WHO policy of referring to generic names should be followed.

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

I do not recommend adding ketotifen to the EML as there is no public health need for this product. Its cost effectiveness has not been established though it is fairly cheap in India and the generic product is available.