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

Expert peer review on application for “Ophthalmological preparation: Addition of Ofloxacin”

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      No
   
   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      For the treatment of suspected microbial keratitis; Ofloxacin eye drop has shown comparative efficacy when compared with Gentamicin.

   c. Please provide any additional relevant information with reference

2. Assessment of safety
   a. Have all relevant studies on safety been included
      No
   
   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      For the treatment of suspected microbial keratitis; Ofloxacin eye drop has shown comparative safety profile compared with Gentamicin.

   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)
      Ofloxacin eye drop has not been compared with Gentamicin eye drop from the cost effectiveness point of view.

   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

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
This application is part of six applications submitted by the International Council of Ophthalmology for updating the Ophthalmological Preparations section of the EML. The applications are as following:

   1. Addition of Bevacizumab
   2. Addition of Ketorolac
   3. Addition of Latanoprost
   4. Addition of Ofloxacin
   5. Addition of Azithromycin
   6. Addition of Ketotifen

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

   1. Eye drop of Ofloxacin is an effective and wide spectrum antibiotic against bacterial infections of eye.
   2. Final recommendation: “Add Ofloxacin eye drop to the 21.1 section of the EML with square box indicating a representative medicine from third generation fluoroquinolone antibiotics”.