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 Azithromycin”

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      No. There are other published data regarding this medicine. Four references have been cited by the applicant.
   
   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      For treatment of active trachoma, Azithromycin eye drop twice daily for 2 or 3 days is as effective as current recommended WHO’s treatment (single oral dose of Azithromycin).
   
   c. Please provide any additional relevant information with reference

2. Assessment of safety
   a. Have all relevant studies on safety been included
      No. There are other published data regarding this medicine. Four references have been cited by the applicant.
   
   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 significant differences between safety profiles of Azithromycin drops vs. oral Azithromycin.
   
   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)
      Comparative cost-effectiveness data on Azithromycin drops vs. oral Azithromycin is not available.
   
   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. Current WHO guideline for treatment of trachoma proposes administration of single oral dose of
   Azithromycin.

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. Based on published data eye drop of **Azithromycin** (2-3 days) do not provide superior efficacy
      compared with oral single dose **Azithromycin**
   2. Lack of cost effectiveness study regarding eye drop of **Azithromycin** in comparison with oral dosage
      form.
   3. Oral **Azithromycin** is still recommended medicine by WHO for treatment of trachoma.
   4. Final recommendation: **“Addition of Azithromycin eye drop to the EML requires prior updating of current WHO trachoma control program; SAFE”**.