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

April 8-12 2013

Expert peer review on Histamine 1 receptor antagonists review

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)

   First generation antihistamines (FGAs) such as chorphenamine and diphenhydramine are effective in treatment of allergic rhinitis (AR) and urticaria. Their efficacy has not been compared in randomized controlled trials (RCTs). Second generation antihistamines such as Loratadine have been shown in RCTS to be as effective as FGAs in treatment of AR and urticaria in adults and children

   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)

   FGA’s have significant side effects such as sedation, impairment of cognition and psychomotor performance and anticholinergic side effects. They are contraindicated in the elderly, in children less than 6 years of age and in aircraft operators. Side effects of SGAs have been compared in RCTs with FGAs and placebo and shown to be relatively minimal.

   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)

   The median price of the maximal daily dose of Loratadine is less than that of Chlorphenamine on the MSH drug price indicator. Loratadine is cheaper than the other SGAs Fexofenadine and Cetirizine.

   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)

   30 - 40% of the world’s population is estimated to suffer from allergic conditions. Allergic rhinitis and urticaria are common conditions worldwide that significantly impact the quality of life.

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

   FDA
   British Society For allergy and Clinical Immunology Guidelines 2010
   World Allergy Organization 2009

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

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

   I recommend the following
   Retain chlorphenamine on the EML for adults with an age restriction of 6 years
   Delete chlorphenamine from EMLc
   Add Loratadine tablet (10 mg) and syrup (1mg.ml) to the EML and EMLc with a square box designation
   An age restriction of 2 years and older is recommended for loratadine

   RATIONALE
   FGAs have significant side effects and are contraindicated in elderly and young children. They cause significant sedation and affect cognitive and psychomotor function. Loratadine is as efficacious and as cheap as chlorphenamine and has minimal side effects. It is safe in children and the elderly.