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

April 8-12, 2013

Expert peer review on benznidazole new formulation

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)

      It is the 1st line drug for the treatment of Chagas disease.

   c. Please provide any additional relevant information with reference

      Not commercially available in the USA or Canada, used as an alternative agent in the treatment of Trypanosomiasis Cruzi.

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)

      – It is highly toxic but the side effects manageable.
      – Not recommended during the first trimester of pregnancy.

   c. Please provide any additional relevant information with reference

      The drug information that is available is old – 1994.

3. Assessment of cost and availability
   a. Have all relevant data on cost 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)

      Only manufactured in Brazil.

   c. Please provide any additional relevant information with reference

      No

   d. Is the product available in several low and middle income countries?

4. Assessment of public health need
   a. Please provide the public health need for this product (1-2 sentences)
I have not been able to access information on WHO position on this drug.

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

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

No

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

Recommended for Chagas disease.