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

April 8-12, 2013

Expert peer review on application to add D4T/3TC 6mg/30mg FDC Dispersible

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes √  No  (if no, please provide reference and information)
      Both medicines are included in the WHO Model EML since 2002.

   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

   c. Please provide any additional relevant information with reference

2. Assessment of safety
   a. Have all relevant studies on safety been included
      Yes √  No  (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)

   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 √  No  (if no, please provide reference and information)

   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 dispersible FDC would offer a pricing advantage over combined cost of individual formulations.

   c. Please provide any additional relevant information with reference

   d. Is the product available in several low and middle income countries?  No

4. Assessment of public health need
   a. Please provide the public health need for this product (1-2 sentences)
Even though use of d4T has been phased out as first-line treatment, as of 2010, almost half of children were on this combination in Sub-Saharan Africa.

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 Yes / No

FDA tentative approval.

7. Any other comments?
No

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