Expert peer review on application for adding AZT 60 mg/3TC 30 mg Dispersible Tab

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes ☑ No (if no, please provide reference and information)
      WHO EML lists same FDC, but non-dispersible

   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)

   While there may be limited data on dispersible forms of this FDC, cost comparison to single syrups used in this pediatric age-group shows a 68% reduction in price.

   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)

   The AZT/3TC NRTI backbone accounted for ≈1/3 of first-line treatment in 2010 in low-and-middle income countries. Ease of administration and reduced cost will allow for greater ARV coverage.

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

   Yes, WHO guidelines 2010.

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       No √

   FDA tentative approval.

7. Any other comments?

   No

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

   Approve based on the public health need.