Expert peer review on application to add AZT 60 mg/3TC 30 mg/NVP 50 mg FDC Dispersible Tab

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes √ No (if no, please provide reference and information)
      The FDC is listed on the WHO EML, but not as dispersible tab

   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)

      Discussed in WHO 15th EML Zidovudine/Lamivudine/Nevirapine application.

   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 FDC pricing remains at 0.070 USD per pill. Changing the formulation to a dispersible tablet should have no impact on pricing.

   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)

   Great need for children 0-6 months especially. Can be used in areas with limited potable water. Can be used in breast milk. Much easier to administer, dispense, transport, etc.

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

   Yes, WHO guidelines.

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.