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

April 8-12, 2013

Expert peer review on application to add EFV 200 mg Scored Tab

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes ✓  No  (if no, please provide reference and information)
      EFV dossier submitted to WHO in 2002 and other formulations included in WHO model EML.
   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)
      EFV safety studies submitted in 2002 to WHO.
   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 200mg scored tablet offers a price advantage at USD39/Year over the 100mg and 50mg tabs/caps. It is also advantageous that the scored tablet can be broken into 100mg doses.
   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)

   Even though 90% of the world’s HIV-infected children lived in Sub-Saharan Africa, at the end of 2010 only 23% of those eligible were on treatment.

   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 the product. There is a definite need for the product in Sub-Saharan African especially where most of the affected children are. The product is cost-effective, easy to administer and dose adjustments are simple due to the scored nature of the tablet.