Expert peer review on application to add NVP 50 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)
   NVP has been included in 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)

   Early review of NVP showed a favourable PK profile with BD dosing and absence of major ADRs with NVP use in pediatric ART. Even though the IMPAACT P1060 showed infants were more likely to fail treatment when on a NVP regimen compared to LPV/ri availability and palatability of the latter pediatric formulation remains a challenge in RLS.

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)
   NVP has been included in WHO Model EML since 2002.

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)

   In comparison to NVP 1 mg/ml syrup, this dispersible tabs costs ≈50% less 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)

   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

   FDA tentative approval.

7. Any other comments?

   No

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

   Product should be approved.