Expert peer review on application for the inclusion of ARTESUNATE and MEFLOQUINE (ASMQ) Fixed Dose Combination (FDC) TABLETS 25 / 55 mg and 100 / 220 mg

1. Assessment of efficacy
a. Have all relevant studies on efficacy been included
   Yes
b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
   1. Both artesunate and Mefloquine are essential anti-malarial medicines listed in WHO EML indicating that their efficacy is documented
   2. Last Expert Committee has encouraged development and vigorous testing of FDC in the treatment of malaria
   3. ASMQ seems to be as effective as combination of loose tablets of AS and MQ
   4. ASMQ provided the greatest post-treatment suppression of malaria when effectiveness of five artemisinin combination regimens with or without primaquine in uncomplicated falciparum malaria was evaluated
   5. Data in children limited
c. Please provide any additional relevant information with reference

2. Assessment of safety
a. Have all relevant studies on safety been included
   Yes
b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
   ASMQ is a FDC of AS and MQ which are already included in EML. No new safety issues were found with the FDC
c. Please provide any additional relevant information with reference

3. Assessment of cost and availability
a. Have all relevant data on cost provided
   No data available
   New product
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)
   See above
c. Please provide any additional relevant information with reference

d. Is the product available in several low and middle income countries?

4. Assessment of public health need
   a. Please provide the public health need for this product (1-2 sentences) Recognizing its public health need, last Expert Committee has encouraged development and vigorous testing of FDC in the treatment of malaria

   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?  
   No

7. Any other comments

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

   1. Recommended inclusion of artesunate and mefloquine (ASMQ) fixed dose combination (FDC) tablets 100 / 220 mg  
      Rationale (Refer 1.b)

   2. Not recommended inclusion of artesunate and mefloquine (ASMQ) fixed dose combination (FDC) tablets 25 / 55 mg  
      Rationale – According to the review document, “Based on published data, WHO recommended reconsidering AS+MQ in Africa, with specific concerns regarding toxicity/vomiting in children. To provide additional information DNDi is sponsoring a multicentre, open-label, prospective, randomized, controlled, Phase IV study in Africa, to assess efficacy, safety and pharmacokinetics of ASMQ FDC in ~1000 children with uncomplicated P. falciparum malaria from Tanzania, Burkina Faso and Kenya versus artemether-lumefantrine.”

      Good to wait for the results of the above Phase IV study