Expert peer review on application to add new formulation ferrous salt + folic acid

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes ✓ No (if no, please provide reference and information)

      b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

      Intermittent iron supplementation alone or in combination with folic acid is effective in reducing the risk of anaemia among menstruating women. Intermittent iron supplementation gives a similar rise in haemoglobin concentration as daily iron intake (Fernandez-Gaxiola AC, De-Regil LM. Intermittent iron supplementation for reducing anaemia and its associated impairments in menstruating women. Cochrane Database of systematic Reviews. 2011(12):CD009218. Epub 2011/12/14.)

      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)

      There are no safety studies that have been done.

   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)

      Ferrous sulphate 60mg with 2.8mg Folic acid is not available in the Kenyan market. Folic acid is available in 5mg at 0.0059 USD per tablet, Fefol (ferrous sulphate 45mg, folic acid 5mg) at 0.1USD.

   c. Please provide any additional relevant information with reference
d. Is the product available in several low and middle income countries?  No

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

WHO Guideline: Intermittent iron and folic acid supplementation in menstruating women.

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

7. Any other comments?

No

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

Anemia is prevalent in resource poor countries due to poor nutrition and parasitic infections. Intermittent iron and folic acid supplements would be a cost effective way to reduce the risk of anemia in menstruating women and adolescent girls ultimately improving their immunity, work performance and maternal- foetal outcomes when they become pregnant. I would therefore strongly recommend that intermittent Iron and Folic acid be included in the EML.