Expert peer review on Antiulcer Medicines.

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)
      Proton Pomp Inhibitors are superior to H2 receptor antagonists in terms of symptoms relief, healing of ulcers and prevention of recurrence, but the later are also quite efficient and have a faster onset of action time. Oral PPIs are maximally absorbed and hence effective if administered on an empty stomach whereas the H2RAs do not have this constraint. Ranitidine (cheap H2RA) already has a parenteral form whereas omeprazole (cheap and prototype PPI) does not have an injection form, which can be a problem if need arises in poor and medium income countries.
   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)
      Both PPIs and H2RAs are quite safe with few side effects, but in pregnancy and incidentally where GERD has a high prevalence, Ranitidine is quite safe having a class “B” classification by the FDA, while omeprazole is class “C”. The other more expensive PPIs are class “B”. Ranitidine is compatible with the ant platelet clopidrogel while PPIs are not
   c. Please provide any additional relevant information with reference

3. Assessment of cost and availability
   a. Have all relevant data on cost and cost-effectiveness been provided?
      Yes
   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)
      Ranitidine is generally cheaper than omeprazole and other PPIs and is generally available and affordable even in poor and medium income countries. IV Esomoprazole (Nexium) a PPI is quite expensive and not generally available. Parental Ranitidine exits and is available even in developing countries.
   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)
      Peptic Ulcer Disease, Gastro- esophageal Reflux Disease, Dyspepsia and Heart burn are common pathologies worldwide affecting millions of people, poor or rich, children all alike
b. Do guidelines (especially WHO guidelines) recommend this product? If yes, which ones? List 1 or 2 international preferable
   Yes Already in WHO EML.

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

7. Any other comments

8. What is your recommendation to the committee (please provide the rationale)
   I agree with Dr Leontiadis and Dr Yuan that Ranitidine stays on the WHO EML and EMLc
   Its effectiveness in treating GERD, NUD and other forms other of dyspepsia, even if inferior to PPIs is not in doubt. Its rapid onset of action and sustained relief of symptoms, the fact that it can be taken at any time on a full or empty stomach, its low cost and availability even in low income countries and lack of safety concerns even in pregnancy makes it a medicine still much solicited. In some situations, it is preferred to PPIs
   It has a parental form which can be very useful even when Oral PPIs are contraindicated. Moreover it is an alternative where PPIs are not tolerated.