EXPERT REVIEW No.1

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

April 8-12 2013

Expert peer review on application for 7.1% chlorhexidine digluconate solution or gel

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Not sure – GRADE Tables and search strategy not available
   
   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

   3 community based RCTs in Nepal, Bangladesh, Pakistan


   Reduction in mortality about 20%

   GRADE tables not available

   c. Please provide any additional relevant information with reference

2. Assessment of safety
   a. Have all relevant studies on safety been included
      Yes, to my knowledge
   
   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

   hypersensitivity reaction main concern

   c. Please provide any additional relevant information with reference

3. Assessment of cost and availability
   a. Have all relevant data on safety 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)

   affordable
c. Please provide any additional relevant information with reference

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

Gel is manufactured in Nepal, liquid will soon be available through UNICEF, 2 additional manufacturers interested in producing the 7.1%

4. **Assessment of public health need**
   a. Please provide the public health need for this product (1-2 sentences)

   Yes, approximately 13% of newborn deaths due to sepsis.

   b. Do guidelines (especially WHO guidelines) recommend this product? If yes, which ones? List 1 or 2 international preferable

   A 1999 WHO document is cited to support use of topical antimicrobials, 2012 WHO consultation also cited, no guideline yet

5. **Are there special requirements for use or training needed for safe/effective use?**
   If yes, please provide details in 1-2 sentences

6. **Is the proposed product registered by a stringent regulatory authority?**
   Yes in Nepal, country by country approach to regulation is suggested in application

7. **Any other comments**

   Current listing is: Chlorhexidine Solution: 5% (digluconate); 20% (digluconate) (needs to be diluted prior to use for cord care)

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

   List: 7.1% chlorhexidine digluconate solution or gel, delivering 4% chlorhexidine for umbilical cord care

   Previous main concern was availability of the formulation and this has now improved