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

April 8-12 2013

Expert peer review on application for deletion of misoprostol for prevention of postpartum haemorrhage

1. Assessment of efficacy
a. Have all relevant studies on efficacy been included
   Yes
   The application identified the same four key studies examined in the unedited report of the 18th Expert Committee on the Selection and Use of Essential Medicines (1): Walraven et al. 2008 (2; reporting on the same RCT as Walraven et al. 2005 (3)); Hoj et al. 2005 (4); Derman et al. 2006 (5); and Mobeen et al. 2010 (6). These studies are also included in the recent Cochrane Systematic Cochrane Review.

b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
   The application does not interpret the included studies in the same way as the Cochrane review (updated 2012). However, the Cochrane review assesses risk of bias of all included studies and conduct sensitivity analyses, so the differences in the methodology of the included studies are taken into account. While the Cochrane review notes weaknesses in individual studies, the overall effect is robust. Oral or sublingual misoprostol compared with placebo is effective in reducing severe PPH (oral: seven trials, 6225 women, not totalled due to significant heterogeneity; sublingual: risk ratio (RR) 0.66; 95% confidence interval (CI) 0.45 to 0.98; one trial, 661 women) and blood transfusion (oral: RR 0.31; 95% CI 0.10 to 0.94; four trials, 3519 women). The review also shows that, based on the evidence, oxytocin, when available and practical, is the uterotonic of choice.

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)
   Not discussed in application

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 safety 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)

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)

not discussed in application

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

Yes

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

7. Any other comments

Current listing in EML: “** For management of incomplete abortion and miscarriage, and for prevention of postpartum haemorrhage where oxytocin is not available or cannot be safely used.”

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

Retain the current listing on EML