Expert peer review on application for Dexamethasone – New indication

Indication: Accelerating lung maturation in preterm babies

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)
      Not applicable as no drug is listed in the EML for the indication
   c. Please provide any additional relevant information with reference – None

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)
      Not applicable as no drug is listed in the EML for the indication
   c. Please provide any additional relevant information with reference – None

3. Assessment of cost and availability
   a. Have all relevant data on cost and availability 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) –
      Not applicable as no drug is listed in the EML for the indication
   c. Please provide any additional relevant information with reference:
      In 2011, in the public health sector, we have supplied 556257 ampoules of dexamethasone Injection (8mg in 2ml Ampoule). The total cost was 32320 USD. The unit cost (one ampoule containing 8 mg in 2 ml) = 0.06 USD and 4 such ampoules will be 0.24 USD (unpublished data)
   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):
It reduces morbidity, mortality and economic burden of pre-term births. Acceleration of lung maturation by ACS will reduce admissions to neonatal intensive care units, thus the beds can be utilized for other priority admissions.

b. Do guidelines (especially WHO guidelines) recommend this product? If yes, which ones? List 1 or 2 international preferable – Yes (WHO, ACOG, RCOG, NIH, IPA – Section 9.2 in the review)

5. Are there special requirements for use or training needed for safe/effective use?
   No
   Cost of accessories for injection, skilled person to inject the medicine.

6. Is the proposed product registered by a stringent regulatory authority?
   Yes, but not for this indication.

7. Any other comments

8. What is your recommendation to the committee (please provide the rationale)
   Recommended to add for the new indication.
   Rationale:
   1. Public health importance -Prevention of a major complication of premature birth will have a considerable impact
   2. Efficacy and safety documented
   3. Recommended in WHO and other international guidelines
   4. Already listed in other sections
   5. Cost effectiveness