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

**April 8-12 2013**

**Expert peer review on Antiarrhythmics (Review) - Children**

1. **Assessment of efficacy**
   a. Have all relevant studies on efficacy been included
      Yes (but evidence is limited in the literature given the rarity and extremes of seriousness (majority are mild, minority are life threatening) of the condition

   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      1. Not applicable. It is a review of the whole section. There is no drugs listed in the EMLc under this section for comparison
      2. Data may have to be extrapolated from adult studies
      c. Please provide any additional relevant information with reference – None

2. **Assessment of safety**
   a. Have all relevant studies on safety been included
      Yes (but evidence is limited in the literature given the rarity and extremes of seriousness (majority are mild, minority are life threatening) of the condition

   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      1. Not applicable. It is a review of the whole section. There is no drugs listed in the EMLc under this section for comparison
      2. Data may have to be extrapolated from adult studies
      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
      No (See below under recommendation)

   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. It is a review of the whole section. There is no medicine s listed in the EMLc under this section for comparison
      c. Please provide any additional relevant information with reference – None

   d. Is the product available in several low and middle income countries? – Yes (They are listed in EML for adult use)

4. **Assessment of public health need**
   a. Please provide the public health need for this product (1-2 sentences)
1. Arrhythmia are very rare in children
2. However, some are life threatening and require emergency medical management

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

The Review has found two guidelines for management of arrhythmias in children: American Heart Association and Australian and New Zealand Resuscitation Councils – Medicines recommended are epinephrine and Amiodarone (both guidelines are for paediatric resuscitation)

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

Acute use: Emergency resuscitation skills and necessary emergency equipments

Maintenance use: Paediatric cardiology expertise for chronic use *

*For Amiodarone, adult use – “Amiodarone should be administered only by physicians who are experienced in the treatment of life-threatening arrhythmias who are thoroughly familiar with the risks and benefits of amiodarone therapy, and who have access to laboratory facilities capable of adequately monitoring the effectiveness and side effects of treatment. (FDA)

6. Is the proposed product registered by a stringent regulatory authority? -
   Yes     No

The review has identified two drugs; epinephrine and Amiodarone (FDA)

   1. Epinephrine for adult and children use (cardiac arrest is accepted as an indication).
   2. Amiodarone – Children - efficacy and safety not established

7. Any other comments

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

   1. Given the rarity of the condition in children, getting evidence on efficacy and safety will be a problem. Data may have to be extrapolated from adult studies.
   2. Bisoprolol, digoxin (oral liquid dosage form is listed), epinephrine, lidocaine, verapamil and amiodarone are listed in Adult EML. Recommend adding epinephrine and digoxin under antiarrhythmic in EMLc. Both are listed in some other sections in EMLc.
   3. Generating data on incidence and causes of paediatric arrhythmias in developing countries will be useful