Expert peer review on application for ANTIARRHYMIC DRUGS

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes

      There are studies on efficacy of antiarrythmic medicines (amiodarone, sotalol, flecainid...)

   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

      Amiodarone and antiarrythmic medicines have efficacy in cardiac arrhythmic treatment, prolonging potential duration in atria and ventricle muscle and in prevention of cardiac sudden death. Antiarrythmic medicines can be used single or together with (implantable cardiac devices, ICD) or ablation

   c. Please provide any additional relevant information with reference

      1. CASCADE study (Am J Cardiol. 1991 Mar 15;67(7):578-84): amiodarone is more effective than the other antiarrythmic medicines in prevention of sudden cardiac death in heart diseases patients.

      2. AMIAT, CAMIAT study (Lancet. 1997 Mar 8;349(9053):675-82.): in comparison with placebo amiodarone reduces sudden cardiac death and decreases the frequency of ventricular fibrillation but could not decrease the death prevalence in myocardiac infarction patients.

      3. AFFIRM study (J Am Coll Cardiol. 2004 Apr 7;43(7):1201-8.): amiodarone is more effective than sotalol and group I antiarrythmic medicine (procainamide, disopyramid...) in maintain the sinus frequency in the atrial fibrillation patients.

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)

      Antiarrythmic medicines may lead the bradycardia and other cardiac disturbances (ventricular fibrillation...) and thyroid function disturbances

   c. Please provide any additional relevant information with reference

3. Assessment of cost and availability
   a. Have all relevant data on cost 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)
   There are no cost effectiveness asessement in Vietnam

c. Please provide any additional relevant information with reference d. Is the product available in several low and middle income countries?
   Amiodaron, Sotalol and antiarrythmic medicines are available in middle and low income countries as generic products

4. Assessment of public health need
a. Please provide the public health need for this product (1-2 sentences)
   The morbidity of heart diseases increases in the population in recent years. Treatment of heart diseases based on cost-effectiveness balance becomes a public health need in many countries specially in low and middle income countries.

b. Do guidelines (especially WHO guidelines) recommend this product? If yes, which ones? List 1 or 2 international preferable
   Health Service Research (HSR)/American College of Cardiology (ACC)/American Heart Association (AHA)/European Society of Cardiology (ESC) recommend amiodarone indication for maintaining sinus frequency in ventricular arrhythmic patients

5. Are there special requirements for use or training needed for safe/effective use? If yes, please provide details in 1-2 sentences
   Prescribing antiarrythmic medicines is one of the most complicated issues in clinical practice of cardiology.
   The antiarrythmic medicines should be prescribed only by skilled and specialized cardiologists and clinicians

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)
   Amiodarone could be listed in EM List due to its efficacy, low cost and availability