Expert peer review on application for Streptomycin complementary list

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes – includes evidence summary from guideline, only one relevant trial identified, no assessment of risk of bias of this trial
   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

      From application:

      “Kansoy et al (1996) compared intermittent short course chemotherapy of SM, RMP and INH for two weeks followed by INH and RMP twice weekly for 8.5 months for pulmonary TB with conventional chemotherapy consisting of SM for 40 days, RMP for 9 months and INH for 12 months. At six months of therapy response to treatment was complete in both groups.”

   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)

      No, safety concerns mentioned, but studies not cited
   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

7. Any other comments

Main rational for move to complementary list is that streptomycin not recommended for first line therapy for TB in recent WHO guideline: “Streptomycin should be reserved for the treatment of multi-drug resistant tuberculosis in children with known drug susceptibility to this medicine”

Complementary list is for medicines that require specialty care or facilities where these multi drug resistant patients are more likely to be. There is lack of evidence to support broader use.

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

Recommend: move to complementary list