Expert peer review on application for moving streptomycin to complementary list

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)

   Streptomycin is no longer a first line medicine for pulmonary tuberculosis or tuberculous lymphadenitis. There are safer more efficacious oral alternatives available.

   c. Please provide any additional relevant information with reference

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)

   Streptomycin belongs to aminoglycosides which have toxicities related to the class such as ototoxicity.

   c. Please provide any additional relevant information with reference

3. Assessment of cost and availability
   a. Have all relevant data on cost been provided
      Not applicable

   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)

      It is required in MDR-TB in children with known susceptibility to streptomycin.

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

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

The medicine has to be injected and the person delivering it has to be trained to give intramuscular injections. Sterile precautions must be taken when injecting.

6. Is the proposed product registered by a stringent regulatory authority?
   Yes

7. Any other comments

The earlier WHO 2006 pediatric guidelines recommended HRZS for meningitis instead of HRZE; but the 2010 update, based on which the present application is made, says that HRZE to be used in TB meningitis as well. Ethambutol toxicity is uncommon in children and hence the present change of shifting streptomycin to the complementary list is reasonable.

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

Streptomycin may be moved to the complementary list as it is not a first line medicine for category 1 patients.