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

**April 8-12 2013**

**Expert peer review on application for deletion of haloperidol and chlorpromazine from the EMLc**

1. **Assessment of efficacy**
   a. Have all relevant studies on efficacy been included
      - Yes ✓ No (if no, please provide reference and information)

   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      
      The question here is of public health relevance, not efficacy.

   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)

   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      
      The question here is of public health relevance, not safety, although concerns have been raised.

   c. Please provide any additional relevant information with reference

3. **Assessment of cost and availability**
   a. Have all relevant data on cost and availability 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)
      
      The question here is of public health relevance, not cost-effectiveness.

   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)

The proposal has questioned the public health relevance of including agents for the management of psychosis in children under 12 years of age.

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

The existing mhGAP-IG evidence review strongly recommended against the use of these agents: “WHO does not recommend using pharmacotherapy for behavioural problems except for ADHD after a first trial with psychological interventions does not prove effective”.

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

N/a

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

7. Any other comments

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

The recommendation in the proposal that haloperidol and chlorpromazine be removed from the EMLc, as psychosis is very rare in prepubescent children, whereas psychotic experiences (which are more common) are transitory and self-remitting in the majority of cases, is supported. In addition, it was pointed out that the use of these agents in managing behavioural problems of children would considered an off-label use.