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 EMLc

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)
   Not applicable – for deletion
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)
   Children on haloperidol and chlorpromazine are prone to sedation, extrapyramidal syndrome (EPS), withdrawal dyskinesia and tardive dyskinesia
c. Please provide any additional relevant information with reference

3. Assessment of cost and availability
a. Have all relevant data on safety provided
   For deletion – 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)
   Psychosis is very rare in children
b. Do guidelines (especially WHO guidelines) recommend this product? If yes, which ones? List 1 or 2 international preferable
   No
5. Are there special requirements for use or training needed for safe/effective use?
If yes, please provide details in 1-2 sentences

Yes. The indications are very few, side effects are many and needs to be used with extreme caution in children.

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)

I recommend withdrawal of haloperidol and chlorpromazine from the EMLc for the following reasons

Psychosis is very rare in children less than 12 years of age. Children are at higher risk of side effects of these drugs. There is a risk of these drugs being used for control of behavioral problems in children.