Expert peer review on application for “Addition of Hydromorphone to 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)
      Hydromorphone has comparative safety and efficacy profile compared with Morphine.
   
   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)
      Hydromorphone has comparative safety and efficacy profile compared with Morphine.
   
   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
      No information regarding availability of medicine in low and middle income countries provided.
   
   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).
      No information is available.
   
   c. Please provide any additional relevant information with reference
   
   d. Is the product available in several low and middle income countries?
      Availability of Hydromorphone in low and middle income countries is not as wide as morphine.

4. Assessment of public health need
   a. Please provide the public health need for this product (1-2 sentences)
      Hydromorphone is an alternative to Morphine for management of persisting pain when Morphine is not available or effective.
b. Do guidelines (especially WHO guidelines) recommend this product?

5. Are there special requirements for use or training needed for safe/effective use?
   Yes, general training for administration of narcotic medicines are required.

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

7. Any other comments
   In order to align the EMLc with the recently published guidelines by WHO for management of persisting pain in children Dr Willem Scholten, Team leader, Access to Controlled Medicines and his colleagues have submitted three application as following to revise the EMLc:
   1. Addition of new formulation for Morphine
   2. Addition of Hydromorphone
   3. Addition of Oxycodone.

8. What is your recommendation to the committee (please provide the rationale)
   1. Due to comparative safety and efficacy profiles of Morphine, Hydromorphone and Oxycodone in order to keep the EMLc as short and simple as possible my suggestion is to keep Morphine with diverse dosage forms as the lead medicine in the list with square box indicating for possible replacement /addition with the other alternatives including Hydromorphone and Oxycodone.