19th Expert Committee on the Selection and Use of Essential Medicines
April 8-12; 2013

Expert peer review on application for “Addition of new formulation of Morphine 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)
   N/A. This is a proposal for new dosage form.

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)
   N/A. This is a proposal for new dosage form.

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.

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)
   N/A. This is a proposal for new dosage form.

c. Please provide any additional relevant information with reference

d. Is the product available in several low and middle income countries?
   Proposed new formulation is not readily available in low income countries.

4. Assessment of public health need
a. Please provide the public health need for this product (1-2 sentences)
   New proposed formulation will improve availability and perhaps compliance for the patients.
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 for the proposed new formulation as well.

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)
   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 a square indicating for possible replacement/addition with the other alternatives including Hydromorphone and Oxycodone

<table>
<thead>
<tr>
<th>Current listing for Morphine</th>
<th>suggested addition by applicant</th>
<th>reviewer proposal for final listing:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection: 10 mg (morphine hydrochloride or morphine sulfate) in 1-ml ampoule. Oral liquid: 10 mg (morphine hydrochloride or morphine sulfate)/5 ml. Tablet: 10 mg (morphine sulfate). Tablet (prolonged release): 10 mg; 30 mg; 60 mg (morphine sulfate).</td>
<td>Granules (slow-release; to mix with water): 20 mg, 30 mg, 60 mg, 100 mg, 200 mg (morphine sulfate) Tablet (slow-release): 100 mg, 200 mg (morphine sulfate or hydrochloride)</td>
<td>Injection: 10 mg (morphine hydrochloride or sulfate) in 1-ml ampoule. Oral liquid: 10 mg (morphine hydrochloride or sulfate)/5 ml. Tablet: 10 mg (morphine sulfate). Tablet /Granules (slow release): 10 mg to 200 mg (morphine hydrochloride or sulfate).</td>
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