(1) Does the application adequately address the issue of the public health need for the medicine?
Yes

Please provide brief details:
The application is for a change in the manner (wording) in which oxycodone and hydromorphone are listed in the 19th EML and 4th EMLc.

(2) Have all important studies that you are aware of been included in the application?

Not applicable.
Oxycodone and hydromorphone were considered in 2013 and were added to the EML and EMLc.

(3) Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed use?
Yes

Briefly summarise the reported outcomes (e.g. clinical, surrogate, other) and comment, where possible, on the magnitude of clinical benefit associated with use of the medicine:

(4) Is there evidence of efficacy in diverse settings and/or populations?
Yes

Please provide brief details:

(5) Has the application adequately considered the safety and adverse effects of the medicine? Are there any adverse effects of concern, or that may require special monitoring?
Yes

Please provide brief details:
ADDITIONAL CONSIDERATIONS:

(6) Are there special requirements or training needed for the safe, effective and/or appropriate use of the medicine?

Yes

Please provide brief details:
Storage as well as ordering, transport regulations have to be fulfilled.

(7) Are there any issues regarding the registration of the medicine by regulatory authorities? (e.g., recent registration, new indications, off-label use)

No

Please provide brief details:

(8) Is the medicine recommended for use in a current WHO GRC-approved Guideline (i.e., post 2008)?

Yes

Please provide brief details:

(9) Please comment briefly on issues regarding cost and affordability of this medicine.

These are costlier than morphine.

(10) Any additional comments?

The wording of the 19th Model List and the 4th Model List for Children state “alternatives limited to hydromorphone and oxycodone” and the application is a request for a change to be made such as “as an example of a class” and that a footnote be added that “two or more alternatives to morphine should be available.” The application also states “but there is not any scientific reason for such limitation to these two opioids only, and also there is no reason to prefer these two alternatives over several other alternative opioids”. This suggests that other opioids may also be substituted here instead of hydromorphone or oxycodone. However, in 2013, the expert committee deliberated and approved of only hydromorphone and oxycodone and not any of the other opioids. There was no evidence presented that any other opioid will be as efficacious or useful in severe pain or in palliative care. Hence, it will not be appropriate to include all opioids here as a class.

The EML core list is a list of minimum medicine needs for a basic health care system. Adding a foot note that “two or more alternatives to morphine should be available” violates the basic tenet of the EML. The storage and other procedural formalities for opioids is very
stringent in almost all countries. Increasing the number of opioids on the list may strain the weaker supply chain systems especially in LMIC which will jeopardize the other medicines.

(11) Please summarise the action you propose the Expert Committee takes.

I propose that the Expert Committee should not include the changes suggested.