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

April 8-12 2013

Expert peer review on application for inclusion of a new heading “Palliative Care”

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes  No  (if no, please provide reference and information)
      n/a
   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      n/a
   c. Please provide any additional relevant information with reference
      n/a

2. Assessment of safety
   a. Have all relevant studies on safety been included
      Yes  No  (if no, please provide reference and information)
      n/a
   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      n/a
   c. Please provide any additional relevant information with reference
      n/a

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)
      n/a
   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
   c. Please provide any additional relevant information with reference
d. Is the product available in several low and middle income countries?

4. Assessment of public health need
a. Please provide the public health need for this product (1-2 sentences)

n/a

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

n/a

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

n/a

7. Any other comments

n/a

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

The heading structure of the WHO Model EML has long been regarded as somewhat idiosyncratic, having presumably evolved from the Table of Contents of a standard text on pharmacology. The presence of absence of a particular heading should therefore not be interpreted as a comment on the priority (or lack thereof) assigned to the management of any particular condition. Instead of making piecemeal changes such as that advocated in this proposal (however compelling), it is recommended that a more deliberate and wide-ranging review of the List structure be considered. One potential approach would be to use the WHO ATC structure as the starting point. However, the feasibility of alternative structures also needs to be examined before a final decision is made. It will still be necessary to annotate some entries to indicate that they are intended for one specific indication and not others (examples may include the laxatives listed, for instance).

That said, the arguments advanced in this proposal are compelling, and the need to provide a visible recognition of palliative care as a neglected clinical speciality and service is fully supported. That palliative care is needed by patients other than those with cancer is also acknowledged. The risk of sending any such “signals” in the restructured List must be avoided.