(1) Does the application adequately address the issue of the public health need for the medicine?
   Yes √ No □

   Please provide brief details:
   The burden of the disease very high 44 to 99 /100,000 population with a high mortality of 9.6% in developed countries and the mortality is even expected to be higher in the developing countries.

(2) Have all important studies that you are aware of been included in the application?
   Yes √ No □

   Please provide brief comments on any relevant studies that have not been included:

(3) Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed use?
   Yes √ No □

   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:
   It identified the various mechanism of PPIs action i.e. Decreasing PH makes it unfavourable for haemostasis while increasing PH promotes haemostasis.
   It has also been found to be more effective than H2RAs and placebo.
   It improves clinical outcomes:
   Significantly decreases rebleeding risk OR 0.49 95% CI 0.37-0.65,
   Reduced need for surgical intervention and further endoscopic treatment OR 0.6195%CI 0.48-0.78. It also reduces mortality in high risk patients.

(4) Is there evidence of efficacy in diverse settings and/or populations?
   Yes √ No □

   Please provide brief details:
   Its efficacy is seen;
1. In patients with non variceal bleeding
2. Post endoscopic treatment of bleeding ulcers
3. Pre-endoscopic treatment
4. Studies in different countries/continents with similar outcomes

(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 ☑ No ☐

Please provide brief details:
IV omeprazole is used for short term treatment and is safe for that purpose. There is no need for special diagnostic treatment or monitory facility and skills.

ADDITIONAL CONSIDERATIONS:

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

Yes ☐ No ☑

Please provide brief details:
From the studies reported, there is no special requirement or training needed for use of the medication since the drug is safe and studies have shown no adverse effect with short term use.

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

Yes ☐ No ☑

Please provide brief details:
FDA and the European medicine agency have approved the drug

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

Yes ☐ No ☑

Please provide brief details:
WHO guidelines were searched but there were no relevant guidelines
(9) Please comment briefly on issues regarding cost and affordability of this medicine.

The Cost of the IV Pantoprazole twice daily is 7 dollars But the cost of IV Omeprazole is not given here, however this cost of Omeprazole is expected to be lower but will still be expensive for low income countries.

(10) Any additional comments?

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

Recommended to be added to the Essential Medicine List