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

Yes √ No □

The evidence submitted is appearing in regard to the public health need for the clopidogrel on secondary prevention and management of cardiovascular disease particularly ischemic heart disease & Stroke.

- Ischemic heart disease is the largest single cause of mortality and loss of disability-adjusted life years worldwide, with the largest burden occurring in LMICs. The number of deaths due to CVD is projected to rise so that if current trends continue to the year 2030, then 85% of cardiovascular disease-related deaths will occur in Low Middle Income Countries (LMICs)


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

Yes √ No □

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

Yes √ No □

Clopidogrel has demonstrated acceptable safety features and cost-effective way of reducing morbidity and total mortality in patients with acute coronary syndrome and following percutaneous coronary interventions.

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

Yes √ No □

It is apparent evident that penetration and use clopidogrel in LMICs is low compared to High Income Countries (HICs) where 82% of patients in HICs with acute coronary syndrome received clopidogrel compared to only 34% of patients in LMICs

(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 □

Precautionary measures should be exercised in patients with bleeding tendencies/abnormalities and high risk patients such older patients
ADDITIONAL CONSIDERATIONS:

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

- Yes ☐
- No ☑

(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 ☑

(8) Is the medicine recommended for use in a current WHO GRC-approved Guideline?

- Yes ☑
- No ☐

(9) Any additional comments? None

(10) Please summarise the action you propose the Expert Committee to take.

I concur with the applicants
- Clopidogrel should be added to the WHO Model Formulary as the representative of the thienopyridine class of antithrombotic for the treatment of acute coronary syndrome and post percutaneous coronary intervention.
- In addition to aspirin is useful for the treatment of acute coronary syndromes and for ischemic heart disease post percutaneous coronary intervention.

REFERENCES:


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percutaneous coronary interventions: position paper by the Working Group on Thrombosis of the European Society of Cardiology European Heart Journal doi:10.1093/eurheartj/ehr204

