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11th January, 2006.

Response to Assessment Report: Coronary Artery Stents for the Treatment of Ischaemic Heart Disease (Update to Guidance No. 71).

Dear Ms. Fuller,

Eucomed wishes to inform NICE that it fully endorses the British Cardiovascular Industry Association (BCIA) position with regard to the Assessment Report (AR). It is felt that the AR presents an extreme and unrepresentative view of the clinical and cost-effectiveness of drug-eluting stents (DES).

Eucomed sees the 4 following issues that significantly influence the overall conclusion of DES cost-effectiveness in the AR:

- 1.) A conflict of interest within the Assessment Group;
- 2.) The use of the CTC Liverpool data as the foundation for the economic model
- 3.) The definition of DES effectiveness that underpins the AR;
- 4.) The use of the Liverpool data in the identification of patients who are at high risk of repeat revascularisation following stenting and the size of the population at risk

Eucomed is particularly concerned about point one, Conflict of Interest. Indeed the overlap in the authorship of the AR and the Bagust paper¹ means that the AR was never likely to reflect an impartial review of all the evidence. This is a serious conflict of interest that has resulted in an AR biased in its presentation of the type of patients at risk of restenosis, the magnitude of that risk and the consequent cost-effectiveness of DES. Moreover, this paper, methodologically and analytically flawed, is also in contradiction to the large amount of data already published in peer-reviewed journals.

On the second point, the CTC Liverpool data used by the authors is a single centre data. It is not clear what percentage of DES usage already existed in the data collected (the Bagust paper says " during this period CTC made minimal use of DES"), which raises questions regarding adequacy of the dataset for further analysis. Also because it is a single centre data, generalizability of the data to UK population and NHS practice is more than questionable.

On the last two points, we would like to refer further to the BCIA response.

Eucomed believes that the above points raise several important questions about using the current Assessment Report to produce guidance on the usage of coronary artery stents that will impact the lives of thousands of NHS patients in the UK.

Yours sincerely,

Eucomed

¹ Bagust A, Grayson AD, Palmer ND, Perry RA, Walley T (2005). Cost-effectiveness of drug-eluting coronary artery stenting in a UK setting: cost-utility study. *Heart* Apr 14; [Epub ahead of print] <http://heart.bmjournals.com/cgi/content/abstract/hrt.2004.053850v1>.