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15th February 2008

Mr A Dillon CBE
Chief Executive
The National Institute for Health and Clinical Excellence
MidCity Place
71 High Holborn
London
WC1V 6NA.

Dear Mr Dillon,

Request for Factual Corrections to Final Appraisal Determination (FAD): Coronary Artery Stents for the Treatment of Ischaemic Heart Disease (Update to Guidance No. 71).

Cordis welcomes the recommendation that patients with coronary artery lesions longer than 15 mm or vessels less than 3 mm in diameter should be treated with drug-eluting stents (DES). Our analysis of these specific sub-groups from within our own randomised trials shows that these patients are at increased risk of repeat revascularisation when treated with bare metal stents (BMS) and that DES reduce this risk considerably. The company, however, has a number of concerns about the FAD and has submitted an appeal in a separate letter.

We understand that NICE welcomes comments by stakeholders that have identified factual inaccuracies in FADs and associated guidance. This letter brings to your attention a number of factual inaccuracies in the FAD. These inaccuracies are likely to lead to difficulties implementing the guidance and a view that the Institute is either seeking to fix or control the price of BMS or DES, or to establish NHS procurement policy.

Correction 1

The first error relates to use of a £5,000/QALY ICER to determine the cost effective DES price premium.

Section 1.1 of the FAD states that "*Drug-eluting stents are recommended for use in percutaneous coronary intervention for the treatment of coronary artery disease, within their instructions for use, only if: … the price difference between drug-eluting stents and bare-metal stents is no more than £300.*" This appears to be related to the finding reported in Section 4.3.13 of the FAD, which says "*For a price difference of £300 the resulting ICERs were associated with costs per QALY below £5000 for patients with small vessels and long lesions.*"

The Institute's published position with regard to cost effective ranges is stated in Section 6.2.6.10 of the *Guide to the Methods of Technology Appraisal*, which notes that "*Below a most plausible ICER of £20,000/QALY, judgements about the acceptability of a technology as an effective use of NHS resources are based primarily on the cost-effectiveness estimate.*" The Institute has little discretion to deviate from the £20,000 threshold. Provided the ICER is £20,000/QALY or below, cost-effectiveness is the primary basis for determining the acceptability of the technology, and only when the ICER exceeds

£20,000/QALY should the Institute have regard to other factors. Thus, the FAD appears to be in error in using £5,000/QALY to identify the cost effective DES price premium and a factual correction that stated the price premium range associated with ICERs of £20,000/QALY and up to £30,000/QALY would provide consistency with the Institute's published methods. According to the Chief Executive of the Institute, "QALYs are currently the best tool for understanding the opportunity cost of implementing NICE decision, and it is important that this tool is applied consistently."

Section 3.2 of Addendum 7 to the Assessment Report informs this point in the comment *"…the three high risk sub-groups which appear to be cost-effective if the DES price premium is below £400-450 per stent."* Table 3 of this Addendum clearly shows that DESs are cost effective at £20,000-£30,00/QALY in the £400-£450 price premium range. Our own work in developing an economic model that can reproduce the Assessment Group's results within about 2% shows that the high risk sub-groups identified in the FAD fall just below the £20,000/QALY threshold in a price premium range of £387-£407.

We therefore suggest the following amendments on the basis that they are consistent with the Institute's stated methods and remit:

- The reference to DES price premium is removed from section 1.1.
- The £300 point estimate of DES price premium be replaced with "*in the range of £400 to £450*" throughout the FAD.

Correction 2

The second error relates to the statement of a specific BMS price as a basis for the understanding of DES cost effectiveness.

Section 4.3.14 of the FAD states that "*The Committee's decision was based on the understanding that the mean absolute price of a BMS was £131 and that procurement arrangements for DESs at a price difference of £300 was already in place within many NHS regions and achievable across the NHS as a whole.*" There appears to be a misunderstanding here that DES cost effectiveness is dependent on an absolute BMS price of £131. This is incorrect as the structure of the economic model used to inform the Appraisal Committee's decisions (and issued for consultation by the Institute) shows that DES cost effectiveness is largely insensitive to BMS price, but is craven by price premium. DESs will be cost effective in the price premium range of £400 to £450 virtually regardless of BMS price.

We therefore suggest the following amendment:

- Section 4.3.14 be amended to read "*The Committee's decision was based on the understanding that procurement arrangements for DESs at a price difference of £400 to £450 was already in place within many NHS regions and achievable across the NHS as a whole.*"

It should also be noted that newer generation BMSs tend to be more expensive but are preferred for complex anatomy because they may access coronary artery lesions that older devices cannot. If the use of these devices were excluded by statement of an absolute BMS price, clinicians may not have access to the BMS that is most appropriate for these complex cases. The BMS pricing information provided by NHS professionals in the public consultation on the ACD reflects the differences between older and newer BMS technology, although this information does not appear to have been presented in the FAD.

We suggest that sections 3.6 and 4.2.12 be amended to include the statement:

- "*However, evidence received from NHS professionals during the public consultation on the ACD suggests that newer generations of BMS are procured at higher prices than the PASA average.*"

NHS Trusts often procure a whole range of PCI-related consumables on the same tender and they should continue to have the discretion to make decisions on the basis of best overall value, whilst being mindful that the DES price premium should fall within the cost effective range, rather than being directed to specific prices for individual line items. Cost effective ranges thus represent the best opportunity for effective implementation of the new guidance.

I look forward to hearing from you in due course.

Yours sincerely,