NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Appeal Hearing

Drug-eluting stents for the treatment of coronary artery disease (part review of NICE technology appraisal guidance 71).

Decision of the Appeal Panel

Introduction

1. An Appeal Panel was convened on 14th April 2008 to consider an appeal against the Institute's Final Appraisal Determination (FAD) to the NHS, on the use of drug-eluting stents for the treatment of coronary artery disease.

2. The Appeal Panel ("the Panel") consisted of Mr. Jonathan Tross (non-executive director of the Institute and chair of the Panel), Professor Sir Michael Rawlins (chair of the Institute), Professor Patrick Morrison (non-executive director of the Institute), Mr. Peter Sanders (lay representative), and Dr Kate Lloyd (industry representative). All members confirmed they had no interest to declare in respect of the appeal under consideration. Mr. Julian Gizzi (Beachcroft) was in attendance as a legal adviser to the Panel.

3. The Panel considered an appeal submitted by Cordis (UK) (a Johnson and Johnson Medical Ltd company). Cordis was represented by Dr Steve Fearn, Mr. Mike Wallace, Dr David Brickwood, Mr. Adrian Griffin and Mr. Grant Castle and in this decision is referred to as "the Company".

4. In addition the following individuals involved in the appraisal were present and available to answer questions from the Panel: Professor David Barnett (chair of the Appraisal Committee), Dr Carole Longson (Health Technology Evaluation Centre Director), Professor John Cairns (member of the Appraisal Committee), and Ms Joanna Richardson (Technical Lead).

5. There are three grounds on which an appeal can be lodged:

1. Ground 1.The Institute has failed to act fairly and in accordance with the published procedures as set out in the Institute's Guide to the Technology Appraisal Process;
2. Ground 2. The Institute has prepared guidance that is perverse in light of the evidence submitted;
3. Ground 3. The Institute has exceeded its legal powers.

6. The chair of the Appeals Committee (Mr Mark Taylor), in preliminary correspondence, had confirmed that the appellant had potentially valid grounds of appeal in relation to all three grounds. The Company also submitted a further letter dated 15th February 2008 requesting what they described as factual corrections to the FAD. The Panel noted that this further letter, and in particular the request for alternative wording in the FAD, significantly overlapped the material in the formal appeal and accordingly considered its contents as part of the appeal.

7. The Final Appraisal Determination ("the FAD") considered at this Appeal provides guidance on the use of drug-eluting stents for the treatment of ischaemic heart disease.

8. The Panel considered each ground in turn beginning, at the request of the Company, with Ground 3.

Ground 3. The Institute has exceeded its legal powers.

9. The Company argued that, by recommending a price differential between the DES and BMS of no more than £300, and by stating a reference BMS price of £131, the Institute is either seeking to fix or control the price of BMSs or DESs, or to establish NHS procurement policy. Both are in excess of the Institute's powers and remit.

10. The Company argued further that the NICE documentation makes clear that is not able to make recommendations on pricing of technology. The power to set price controls rests with the Secretary of State; and NHS procurement policy is properly the function of the National Health Service Purchasing and Supply Agency ("PASA"). The Company submitted that the specific linking of recommended use to a maximum price premium was outside NICE's remit and usurped other bodies' functions.

11. Professor David Barnett on behalf of the Appraisal Committee said that the Committee had no wish to set or control prices for these products or to establish procurement policy for the NHS. As the Committee is required to assess cost effectiveness, they do, however, need to have a price for products as an input to the multivariate analysis of cost effectiveness in comparison with alternative technologies. Normally they would include, in the evidence section of the FAD, specific prices for the various technologies.

12. Professor Barnett explained (and it was confirmed by the Company) that the concept of an official list price does not apply in the case of stents. Instead, prices are a matter of local negotiation between the supplier and the relevant NHS authority. Accordingly, the Assessment Group had gathered market evidence, both of the average price for the baseline BMS technology achieved in procurements and of the price premium obtained for DESs.

13. The Company did not dispute that it was reasonable to include evidence of market prices in the assessment, nor did the Company challenge the figure of £300 itself as a differential if that was the market evidence. Their concern was that the price premium was included in the Guidance (Section 1) itself, rather than the evidence section (Section 4) of the FAD. The effect, the Company contended, was that this was already being used in practice as a determinant of the price negotiable in the market and analogous to price setting.

14. The Panel noted the absence of the normal listing of product prices in the FAD. However, it concluded that this is essentially caused by the absence of fixed prices in the market. In other appraisals the recommendation itself might have referred to choosing the least expensive of comparable products, with the price(s) being transparent for procurement purposes in the evidence section of the FAD. However, that was not possible in the absence of set prices that can be listed in the FAD. Clearly, the Committee had to include costs in the assessment. The way they did so – using evidence of average prices and premiums obtainable in what is recognised to be a dynamic market – was reasonable. Since the balance of cost effectiveness of DESs compared to BMSs turns on the comparative price, it is difficult to see how the Appraisal Committee could have framed its recommendation differently. Nor indeed is it clear that a more general statement in the recommendation itself, accompanied by transparency elsewhere in the FAD on the price premium at which cost effectiveness is achieved, would have made much difference in practice.

15. The Panel therefore concluded that the relevant recommendation, including the reference to an acceptable price premium, was not an attempt to set or control prices or to establish procurement policy for the NHS. Rather it reflects the effect of dealing with the way the market for this group of products works, with prices negotiated not fixed by a list price. The Panel did not therefore consider that the proposed guidance exceeded the Institute's legal powers.

16. The Panel therefore dismissed the appeal on this point.

Ground 1. The Institute has failed to act fairly and in accordance with its published procedures.

17. The Company argued that the Institute had based its recommendation that the price difference between the DES and BMS must be no more than £300, on ICERs of less than £5,000 per QALY. The Institute's failure to base its recommendation on an ICER of £20,000 per QALY specified in its own published procedures had, it was alleged, unfairly prejudiced the Company.

18. More particularly, the Company argued that the evidence before the Appraisal Committee (Addendum 7 to the Assessment Report) showed that drug-eluting stents are cost effective at price premiums up to £400-£450 and this should be substituted for the reference to a premium of no more than £300 in the body of the guidance. The Company argued that the analysis using evidence and assumptions contained in a submission from the British Cardiovascular Intervention Society (BCIS) suggested a QALY that could be no more than £5,000 for patients with small vessels or long lesions at a price premium of £300. As this was well below the standard benchmark of a £20,000 cost per QALY benchmark of cost effectiveness, failure to recommend the use of DESs at a wider range of premium cost failed to follow the Institute's own standard criterion for cost effectiveness. Further, the Company argued that DES would fall within the normal ICER range of £20,000-30,000 at a price premium of £400-450 and the published procedures required specific explanation as to why technologies falling with that range were not recommended.

19. Professor Barnett explained that the Committee had considered aspects of the BCIS approach optimistic. The Committee did therefore not accept the cost per QALY estimate of £5000 as it stood. The benchmark assessment (paragraph 4.3.12), on the basis of a £300 price premium, showed costs per QALY for the two high risk groups of £47,000 and £25,000. The Committee

had considered evidence from BCIS on the balance between elective and non-elective interventions and use of antiplatelet drugs which suggested that these figures assessment had been on the conservative side. As a result the Committee had agreed, on balance, to recommend use of DESs for the two high risk groups at a premium of £300 (whereas the Appraisal Consultation Document, using a price premium of £600 had not recommended their use).

20. The Panel considered Professor Barnett's explanation and reviewed the actual wording of paragraph 4.3.13 of the FAD. The Panel concluded that there had not been an unfair departure from the standard approach. The more favourable cost per QALY cited by the Company was associated with a set of parameters provided by the BCIS, which had not been accepted by the Committee. The Committee had not, therefore, departed from the procedures normally used by the Institute and had not acted unfairly.

21. The Panel therefore dismissed the appeal on this point. Nevertheless, to ensure greater clarity, the Panel proposes to the Guidance Executive that the sentence in paragraph 4.3.13 of the FAD line 12 starts: "The Committee was not, however, persuaded that all of the ……."

Ground 2. The Institute has prepared guidance which is perverse in the light of the evidence submitted.

22. The Company argued that:

- the Institute's recommendation that DESs should be used only when the price difference between the DES and BMS is no more than £300 is perverse in light of evidence that DESs are cost effective if the DES price premium is below £400-£450 per stent; and

- the Institute's reliance on a £131 mean absolute price of a BMS and procurement arrangements for DESs at a price difference of £300 has resulted in guidance that is perverse in the light of evidence before it. The economic model shows that DES cost effectiveness is largely insensitive to BMS price.

23. In their evidence, the Company did not challenge the use of the £300 price premium itself, provided it was based on market practice rather then a pre-set criterion to produce a specific result. Nor did they challenge the judgements made on the clinical aspects relevant to the assessment. The Company's concern was the use of a maximum price differential of £300, in the

recommendation in the Section 1 Guidance, which they considered would be used to set prices in the NHS. The price differential reference should be in the evidence section of the FAD (Section 4) rather than in the formal recommendation (Section 1). They were concerned as to the source of the average price of £131 for a BMS and its link to the £300 price differential as setting a de facto BMS price and a DES maximum price.

24. In clarification on the use of the £131 and £300 figures, Professor John Cairns on behalf of the Appraisal Committee said that the Committee had needed to establish, through PASA, a base price for the BMS technology and a comparative price for the DES technology. These were obtained by surveys of NHS Trusts. Without them, it would not have been possible to make an assessment of comparative cost effectiveness of the more expensive DES product range. Professor Barnett commented that the issue remained the absence of clarity on absolute price of the technologies. The Committee did need to establish the cost difference, because without it, they could not have reached a conclusion on relative cost effectiveness. His view was that, whether the precise comparison was in Section 1 or Section 4 of the FAD, was a matter for judgement. However, the price differential and its impact on cost effectiveness needed to be clearly stated, with arguably the same effect wherever it was sited.

25. The Panel considered that the Committee's conclusions had been based on recent market evidence that the mean NHS negotiated price of a BMS was £131; and that a price premium for DESs was negotiable at £300. The Panel did not, therefore, consider that the Committee's conclusions were perverse.

26. The Panel dismissed the appeal on this point. To avoid any misunderstanding, however, the Panel proposes to the Guidance Executive that the sentence in paragraph 4.3.14 of the FAD line 10, be amended thus: "…..the mean absolute price of a BMS, <u>to the NHS,</u> was £131 and that procurement ……".

Conclusion and effect of the Appeal Panel's decision

27. The Panel dismissed the appeal on all three grounds. The Panel advises, however that the text of the FAD be amended as proposed in paragraphs 21 and 26 (above).

28. There is no possibility of further appeal within the Institute against this decision of the Panel. However, the decision of the Panel may be challenged by an interested party through an application to the High Court for permission to apply for judicial review. Any such application must be made promptly and in any event within three months of this decision or the issuing of the Guidance.