

National Institute for Clinical Excellence

HTA secondary prevention of osteoporosis

Findings of the Appeal Panel Friday 22nd October

1. Introduction

- 1.1 An Appeal panel was convened on 22 October 2004 to consider an appeal against the Institute's guidance to the NHS on Bisphosphonates, selective oestrogen receptor modulators and parathyroid hormone for the secondary prevention of osteoporotic fragility fractures in postmenopausal women.
- 1.2 The appeal panel consisted of Dr Susanna Lawrence, chair of the panel and vice chair of the Institute, Mr Mark Taylor and Professor Leon Fine, non-executive directors of the Institute, Dr Robert Donnelly, industry representative, and Ms Jean Gaffin, patient representative.
- 1.3 An appeal was lodged by Eli Lilly and Company Limited, who attended and were represented at the appeal.
- 1.4 In addition the following individuals involved in the Appraisal were present and answered questions from the Panel: Professor David Barnett, Professor Andrew Stephens, Dr Carol Longson, Professor Peter Littlejohns and Mr Meindert Boysen.
- 1.5 Dr Sarah Cumbers, Technology Appraisal Project manager at the Institute, was also present, as was the Panel's legal advisor, Mr Stephen Hocking of Beachcroft Wansbroughs solicitors. As this was the first appeal conducted under the Institute's April 2004 procedures, members of the public who had pre-registered were also present.
- 1.6 The three grounds on which the Panel can hear an appeal are:
 - 1.6.1 the Institute has failed to act fairly and in accordance with its procedures;
 - 1.6.2 the Institute has prepared guidance which is perverse in the light of the evidence submitted; and
 - 1.6.3 the Institute has exceeded its powers.
- 1.7 The Institute's appeal procedures provide for an initial scrutiny stage to confirm that the points of appeal put forward are at least arguably within the permitted grounds of appeal. Before the hearing was convened, the appellant and the chair of the Institute Professor Michael Rawlins were in correspondence on this subject. This was the correct procedure under the Institutes former appeal rules. However as noted above the Institute's appeal procedures have changed, and

under the new procedures this dialogue would have been with Dr Lawrence rather than Professor Rawlins. Accordingly before the appeal hearing began, Dr Lawrence informed the appellant that it would be free to present any or all of its points of appeal as they were originally formulated, or as they were re-formulated in dialogue with Professor Rawlins, entirely at their option. The panel would be mindful of any difficulty this might cause and would be willing to consider a point under appeal ground one, two, or both one and two, as the appellant indicated. The appellant agreed to proceed on this basis.

2. Appeal Ground 1 the Institute has failed to act fairly and in accordance with its procedures

- 2.1 The appellant alleged that NICE's refusal to take into account fully the benefits of raloxifene in preventing breast cancer is inconsistent with its own procedures.

The appellant agreed to consider this point under Ground 2.

The Panel considered on its own motion whether the complaint could be said to have shown a valid appeal point under ground one, namely that this evidence had not been considered at all, or had been given unjustifiably little weight, but concluded this was clearly not the case.

The Panel accordingly dismissed the appeal on this point.

- 2.2 The appellant alleged that the Institute has failed to show transparency in the appraisal process in the following ways.

- 2.3 The appellant alleged that no explanation is provided in the FAD for the exclusion of patients under 65 years from teriparatide treatment

The Appeal Panel questioned the members of the Appraisal Committee and ascertained that the reason for excluding this group of patients was on grounds of cost effectiveness, as clearly stated in the FAD at paragraph 4.3.18. The Panel heard that this conclusion had been reached after consideration of the conclusions of the modelling presented in the Assessment Report, the views of clinical experts, and specific consideration of the effects of the guidance on those with severe disease and multiple risk factors. The Panel was satisfied that the reasons for this recommendation were adequately clear.

The Panel accordingly dismissed the appeal on this point.

- 2.4 The appellant alleged that no explanation is provided in the FAD for the failure to recommend teriparatide treatment for patients intolerant to bisphosphonates or who are unable to comply with the recommendations for their use.

The Panel ascertained from the Appraisal Committee that it did not intend to exclude these patients and that the FAD did not fully represent their conclusions in that regard. The Committee stated that this point could be addressed by the additional wording in FAD 1.4, as follows:

'Teriparatide is recommended as a treatment option for the secondary prevention

of osteoporotic fragility fractures in women aged 65 years and older who have had an unsatisfactory response to bisphosphonates, **or intolerance to bisphosphonates**, (as defined in 1.5 and 1.6 respectively), and:.....

The Appeal Panel recommend that this wording is changed in the FAD, and is included in the Guidance issued to the NHS.

The Panel accordingly dismissed the appeal on this point as the FAD will be altered to reflect the Committee's true conclusion.

- 2.5 The appellant alleged that the evidence of clinical experts, to the effect that there is currently no evidence that raloxifene is effective in preventing non-vertebral fractures, has not been disclosed.

The Appeal Panel confirmed with the Appraisal Committee that the identity of the clinical experts is given in Appendix B of the FAD. The opinions of the clinical experts had been presented in both written and oral submissions to the Appraisal Committee. The Appraisal Committee confirmed that all data presented to them was taken into account. The Appeal Panel considered that paragraph FAD 4.3.12 adequately stated the views of the experts on this point.

The Panel were satisfied that the different conclusions reached for the recommendations of alendronate and raloxifene respectively were due to the consideration all the evidence placed before them, and not just on consideration of the RCTs cited in the FAD.

The Panel accordingly dismissed the appeal on this point

- 2.6 The appellant alleged that no explanation is provided in the FAD for the decision to require multiple fragility fractures and further deterioration in BMD before teriparatide treatment may be prescribed.

The Appeal Panel questioned the Appraisal Committee on the rationale behind the decision, and heard that the Committee's deliberations had addressed the question of when to move from first line to second line treatment. The Committee members explained their conclusions that it was important to give the first line treatment (bisphosphonates) a chance to work, and the preconditions placed upon the use of teriparatide treatment in the FAD reflected this point. The Panel were satisfied that the synopsis presented in 4.3.17 was intended to give a flavour of the issues discussed with the clinical experts.. The Panel concluded that there was sufficient information in the FAD to give a broad understanding of the conclusions reached in recommending the different treatments.

The Panel accordingly dismissed the appeal on this point

- 2.7 The appellant alleged that the views of clinical experts with respect to women with osteoporotic fragility fractures below the age of 65 years referenced at paragraph 4.3.9 of the FAD, have not been disclosed to Lilly.

The Panel ascertained from the Appraisal Committee that the views of the clinical experts had contributed to the lowering of the threshold for treatment from 70 to 65 years. The Committee acknowledged that this specific point was not included in the FAD. The Panel acknowledged that there are inevitably choices about

which specific points of the deliberations are included in the FAD, particularly in the case of expert evidence much of which will be given orally. The Panel was not persuaded that Lilly had been disadvantaged in their presentation of evidence to the appraisal process and, particularly as the views of the experts had contributed to an increase in eligibility for treatment, this omission did not constitute unfairness to the appellants.

The Panel accordingly dismissed the appeal on this point

- 2.8 The appellant alleged that no explanation has been given for the conclusion at paragraph 4.3.14 of the FAD that the long-term risks of raloxifene treatment are uncertain.

This point is also considered under Ground 2, see below.

The Appeal Panel heard from the appellant that the CORE study demonstrated safety during an 8 year follow up phase. The Appraisal Committee agreed that this data had been considered and accepted by the Committee.

The Panel recognised that, although not intended, the current wording in 4.3.14 might imply that there was greater uncertainty or concern regarding the long-term risks of raloxifene treatment than was reflected in the data. The Panel considered that the Committee's evidence was that this was not its intended meaning. The Panel recommend that the point is clarified by the addition of the phrase 'beyond 8 years' to bullet 3 of FAD 4.3.14., so it reads 'the long-term risks of raloxifene treatment beyond 8 years are uncertain'.

Subject to this correction, the Panel dismissed the appeal on this point.

- 2.9 The appellant alleged that no explanation has been provided for the rejection of the views of clinical experts described at paragraph 4.3.17 of the FAD.

This point is considered under Ground 2. The panel of its own motion considered whether the matters complained of raised a valid ground of appeal under ground one but concluded they did not.

- 2.10 The appellant alleged that the FAD does not explain how, if at all, the benefits of teriparatide in terms of reduced back pain have been taken into account in assessing cost-effectiveness.

The Committee members confirmed that the study comparing the effect of teriparatide with that of alendronate in reducing back pain had been considered by the Committee, and taken into account in assessing cost and clinical effectiveness of the two technologies. This is noted specifically in FAD paragraphs 4.1.9.4, and 4.3.16. The Panel concluded that the FAD contained ample information to describe how this study had been taken into account, and the reasons for approaching this data with caution, and the need for more research to establish relative clinical and cost effectiveness, were stated and should have been understood by the appellants.

The Panel accordingly dismissed the appeal on this point.

- 2.11 The appellant alleged that no explanation is provided for the recommendation that several bisphosphonates should be tried, where treatment has been discontinued because of inability to comply or intolerance.

It was self-evident to the Panel from the FAD and the evidence available to the appraisal committee that, given the committee's overall conclusions as regards bisphosphonates and the different regimes and profiles of tolerability of the bisphosphonates, it was appropriate to recommend trying a different bisphosphonate if the first choice was discontinued, before trying an alternative therapy. Furthermore, FAD paragraph 4.3.10 expressly explains the rationale behind this recommendation.

The Panel accordingly dismissed the appeal on this point.

- 2.12 The appellant alleged that no explanation is provided for the conclusion that all the bisphosphonates are treatment options for women with established osteoporosis.

The Panel questioned the Appraisal Committee members on the inclusion of etidronate, despite its accepted weak RCT evidence base. The Panel heard that it was the balance of all the evidence, including observational evidence and expert opinion, that led them to conclude that there was sufficient evidence to justify its inclusion, as stated in paragraph 4.3.7. In addition there was wide variation in patient preference, relating to tolerability. The Panel noted that both arguments for including all bisphosphonates were clearly stated in paragraph 4.3.7. The panel considered that the issues were clear to the appellant.

The Panel accordingly dismissed the appeal on this point

- 2.13 The appellant alleged that no explanation is provided as to how the benefits of raloxifene in relation to blood lipids have been taken into account.

The Panel ascertained that the beneficial effect of raloxifene in relation to blood lipids was considered by the Appraisal Committee, in addition to the other effects on cardiovascular disease events. They noted that the beneficial effect on lipids was specifically mentioned in paragraph 4.1.8.5. In response to direct questioning, the Committee members stated that they considered the effect on blood lipids to be 2nd or 3rd order, compared to the effect of raloxifene on breast cancer. Furthermore they had had to balance any beneficial effect on lipids with the potentially adverse effect of increased thromboembolic events. The Panel considered these issues were adequately expounded in paragraphs 4.2.7.6 and 4.2.7.7 of the FAD.

The Panel accordingly dismissed the appeal on this point

- 2.14 The appellant alleged that no explanation for disregarding the subset of patients with severe prevalent vertebral fractures has been provided.

The Panel heard that the Appraisal Committee were aware of the subgroup analysis, but recognised the limitations of interpreting data divided into subsets. They indicated that the MORE study had not been set up for subgroup analysis, and that any such analysis required all subgroups to be equally considered. The Panel were satisfied that, given the above argument, there was no requirement to explain this point within the FAD.

The Panel accordingly dismissed the appeal on this point.

- 2.15 The appellant alleged that NICE has not followed its own procedures with respect to the hierarchy of evidence relied on.

The Panel noted that no clear reference is made to a hierarchy of evidence within NICE's own procedures, although it is referred to in the Guidance to Manufacturers and Sponsors.

The Appraisal Committee were questioned on this point and confirmed that they adhered to the principle of a hierarchy of evidence. They confirmed that evidence from observational studies had at no time been considered of greater weight than evidence from RCTs. The Committee members elaborated on deliberations regarding the evidence considered for both bisphosphonates and for raloxifene, and confirmed that they had considered the RCT evidence for both, prior to considering observational evidence. They confirmed that, when all the evidence was considered, the evidence for etidronate was more convincing than that for raloxifene. The Committee members acknowledged that it was theoretically possible to come to a different conclusion regarding the significance of relevant data, but this was the essence of comparing differently designed trials, and different types of evidence. They did confirm that they had taken into account all the evidence regarding both drugs, in reaching their conclusions.

The Panel considers that provided the Committee evaluates all relevant evidence it may give it such weight as the Committee may reasonably think fit. The Panel accordingly dismissed the appeal on this point

- 2.16 The appellant alleged that there had been a failure to place adequate weight on the Secretary of State's Directions.

The appellant confirmed in correspondence that the assertion is that the Appraisal Committee 'has failed to take into account the Secretary of State's Directions as required by NICE's procedures.'

The Panel recognised that it was not their role to assess whether 'adequate' weight had been given to the Secretary of State's directions, as the precise weight to be given to those directions is a matter for the committee, but to ensure that they had genuinely been taken into account.

The appellant cited three specific areas as follows:

- 2.17 The Secretary of State's and the Welsh Assembly Government's broad clinical priorities (as set out for instance in national Priorities Guidance and in national Service Frameworks).

The Appeal Panel questioned the Appraisal Committee members regarding the evidence considered, and heard that the whole panoply of evidence placed before them addressed the needs of the elderly population; in other words, that it was impossible to consider the technologies under review without addressing the

needs of the elderly population. The Panel considered that this was amply reflected within the FAD, in particular in Section 2: Clinical need and practice. Specifically, the Panel were informed that NICE guidance published subsequent to any relevant National Service Framework was considered as updating the NSF. The Panel were unable to see how it was possible to assert that the guidance as outlined in the FAD was inconsistent with national priorities, or that the Committee had failed to take into account the Secretary of State's directions on this point.

The Panel accordingly dismissed the appeal on this point

2.18 The degree of clinical need of the patients with the condition under consideration.

The appellant asserted that the guidance represented delayed action in requiring further fractures before changing to second or third line treatment, namely raloxifene or teriparatide. The Appraisal Committee members again asserted that the reasoning behind this guidance was to give the bisphosphonates a chance to work, and that it was inaccurate to cite the guidance as recommending 'delayed action' as the patients were already on first line treatment at this point. The Panel were satisfied that the Committee had considered the degree of clinical need of the patients under consideration.

The Panel accordingly dismissed the appeal on this point

The broad balance of benefits and costs.

The Panel questioned the Appraisal committee as to whether they had taken into account specifically the possible benefits relating to breast cancer and cardiovascular disease with respect to raloxifene, and the benefits of preventing further fragility fractures and disease progression with respect to both technologies. The Panel were satisfied that the Committee had considered these preventive benefits in weighing up the balance of benefit and cost.

The Panel accordingly dismissed the appeal on this point

2.19 The appellant alleged that the division of this appraisal part way through the process and the absence of a proper scope is inconsistent with NICE's procedures and has prejudiced the fairness of this appraisal.

The Panel questioned the Appraisal Committee members as to why the scope had been changed part way through the process. The Committee members explained that after the first ACD was published, the Committee received feedback from a range of stakeholders, including the appellant (correspondence 26th January 2004) indicating that the restrictions on treatment for primary prevention were inappropriately applied. When the Committee met for the third time in February 2004 they concluded that a separate ACD for primary prevention was desirable. However, they were mindful of the extensive work already done in producing the Assessment Report, the subsequent report produced by the Decision Support Unit in October 2003, detailing the cost/benefit analysis of raloxifene with respect to breast cancer and coronary heart disease events. They were aware that the full extent of the evidence base for secondary prevention had already been seen and assessed, and that to abandon the process and begin again would be to needlessly repeat a great deal of work, and produce

unnecessary delay in delivering guidance to the NHS.

As a result the Committee recommended to NICE that the scope was narrowed to address secondary prevention only, and that a separate appraisal be conducted into primary prevention, which could be published at a later date, and could incorporate the outputs of the risk analysis work expected from the WHO and the NICE guideline development group on osteoporosis. NICE accepted these recommendations, and a letter outlining the decision was sent to all stakeholders on 20th February 2004. The appellant responded by letter (dated 9th March 04) where they welcomed the reconsideration of the draft guidance. No concern was raised at this time as to whether the narrowing of the specification might prejudice the appellant or other stakeholders.

The Panel considered the above points, and recognised that, although not ideal, there were sound reasons for adjusting the scope part way through the process. Firstly, the adjustment was only to remove a self contained area from the scope, rather than to introduce a new area into it. Secondly, all the evidence relevant to the reduced scope was already before the Appraisal Committee. Thirdly, the appraisal of that evidence was unaffected by the reduction in the scope, and finally, the appellant had accepted the change at the time. Based on a consideration of these points, the Panel concluded that the appellant had not been prejudiced in any way by this process, and that no unfairness had been caused.

The Panel accordingly dismissed the appeal on this point

However as there was no mention within NICE procedures of how to manage this type of situation, the Panel recommends to NICE that such procedures are reviewed.

3. Appeal Ground 2: The decision in the FAD is perverse in light of the evidence submitted.

As noted above, some of the points which the appellant originally wished to present under ground one were presented under ground two. The panel nevertheless considered whether the material presented could also raise a valid point under ground one.

3.1 The appellant alleged that NICE's refusal to take into account fully the benefits of raloxifene in prevention of breast cancer is inconsistent with its own procedures.

Under this appeal ground the Panel asked itself whether the recommendations in respect of Raloxifene were perverse, having regard to the evidence relating to breast cancer benefit.

The Appeal Panel questioned the Appraisal Committee members as to their assessment of the benefits of raloxifene in preventing breast cancer. The Committee confirmed that they recognised the important effect of raloxifene in preventing breast cancer, that they had commissioned the DSU report specifically to examine the combined beneficial effects of raloxifene in reviewing its cost effectiveness, and on the strength of the findings of the report, had amended the recommendations to include raloxifene as a treatment option. They described the outline of their deliberations, seeking to reach a position where the beneficial breast cancer effect, was neither ignored, nor given overmuch weight bearing in mind that the scope of the appraisal was for the treatment of osteoporosis, not breast cancer. This reasoning was behind the comment in the FAD in 4.3.14 that

breast cancer benefit should not be 'the sole factor' in deciding whether raloxifene is a cost effective option.

The Panel were satisfied that the Committee had taken into account the breast cancer benefits of raloxifene, and had made a reasonable judgment including those benefits in recommending raloxifene as a second line treatment in the light of the balance of benefits and costs.

The Panel accordingly dismissed the appeal on this point.

- 3.2 The appellant alleged that no explanation is provided in the FAD for the decision to exclude patients younger than 65 years from teriparatide treatment, irrespective of the level of clinical need.

Under this appeal ground the Panel asked itself whether the recommendations in respect of teriparatide for the under 65s were perverse.

In response to questioning, the Appraisal Committee members stated that the reason for the cut off point of 65 was cost effectiveness, and that they were aware of the limitations of the economic model presented within the Assessment Report. Because of limitations, including the absence of a risk algorithm, they considered the effect of the model on determining treatment for the full range of patient age and risk factors. They also considered the views of the clinical experts. They acknowledged that there was a small group of patients, namely those under 65 years with multiple risk factors and an unsatisfactory response to bisphosphonates, for whom the guidance left no option for treatment with teriparatide, until they reached the age of 65. In view of the small numbers involved, and the complex health issues facing individuals affected in this manner, the Committee believed it was for the clinician involved to assess the appropriateness of treating outwith the guidance.

The Panel were concerned that the guidance limited treatment options for this small group, but were persuaded that the Committee had not acted perversely in reaching their conclusions, which were valid for the population as a whole, and based on the overall balance of clinical and cost effectiveness. Whilst noting that all guidance issued by NICE is published within the context of recognising the individual responsibility of health professionals to make appropriate decisions, the Panel wished to emphasise the need for individual clinical judgment to determine appropriate treatment for this group.

The Panel accordingly dismissed the appeal on this point.

- 3.3 The appellant alleged that no explanation has been given for the conclusion at paragraph 4.3.14 of the FAD that the long-term risks of raloxifene treatment are uncertain.

The Panel explored the intended meaning behind this point in the FAD, as outlined at paragraph 2.8. With the amended wording as described, the Panel concluded that this was a reasonable statement to be included in the FAD.

Subject to this amendment being made the Panel accordingly dismissed the appeal on this point.

- 3.4 The appellant alleged that no explanation has been provided for the rejection of the views of clinical experts described at paragraph 4.3.17 of the FAD.

The Panel questioned the Committee members, who refuted the assertion that they had rejected the views of clinical experts. Rather, they had taken them into account in considering all of the evidence placed before them, including the expert opinions. They were not bound to agree with the clinical experts. Paragraph 4.3.17 was a summary intended to give a flavour of the experts' recommendations. The Panel concluded that the Committee had not reached a perverse conclusion in the light of the experts' views.

The Panel accordingly dismissed the appeal on this point.

- 3.5 The appellant alleged that it is perverse for the Appraisal committee to place uncritical reliance upon the Assessment Group's cost effectiveness model, despite evident weaknesses.

The Appraisal Committee members acknowledged the limitations of the Assessment Group's model, but were of the opinion that it was amongst the best they had encountered, the limitations being related to the lack of an accepted methodology to quantify risk. The Committee had relied significantly on the AG's model, but not to the exclusion of others: they had considered both the AG's and the appellant's models, and had explored their differences. The Panel were informed that, because of the recognised limitations of the model, the Committee had used the model to frame their thinking, rather than rely on it uncritically. They had tested the model against a number of different scenarios, and in each case the different variables had led to further limitation of the number of people eligible for treatment. In other words, they managed the broad confidence interval by defining the treatment group using the more optimistic margin.

The panel considered the particular issues raised in the appeal. Regarding the time horizon of 10 years, paragraph 4.3.5 recognises that uncertainties around health effects support reliance on the 10 year (shorter) time horizon. The Assessment Group recognised potential inaccuracies due to gaps in the evidence base

Regarding the use of a similar fall time for bisphosphonates and raloxifene, the Panel heard that the Appraisal Committee had rechecked their position upon receipt of the additional evidence supplied by the appellants in April 2004 (Bagger et al. Bone 2004; 34;72). This new evidence, potentially increasing the cost effectiveness of raloxifene, when weighed up with all the other evidence before the Committee, did not change the guidance recommended by the committee.

These and the other particular examples cited in the FAD were considered by the Panel. The Committee members acknowledged the range of uncertainties itemised, and confirmed that these had all been considered and assessed against the model. They asserted that the cumulative effect of these parameters could, if certain hypothetical values were allocated, produce improved overall cost effectiveness, but that this was only one possible outcome. The Panel concluded that the collective uncertainty could not be interpreted in such a narrow way, and that the Committee had acted reasonably in relying on the Assessment Group's model to give the best estimates of cost effectiveness, given the limitations of data available.

The Panel accordingly dismissed the appeal on this point.

- 3.6 The appellant alleged that the FAD is inconsistent in its conclusions regarding the effects of teriparatide on non-vertebral fractures and is therefore perverse.

The Committee members accepted that the wording in the FAD was inconsistent, but stated that it did not fully reflect their deliberations, and suggested to add the word 'grouped' be added to the second sentence in FAD paragraph 4.3.16. Thus amended, paragraph 4.3.16 reads 'the Committee considered that evidence from RCTs showed that teriparatide was effective in preventing vertebral and grouped non-vertebral fractures in women with severe osteoporosis, compared with placebo.

Subject to this correction being made the Panel accordingly dismissed the appeal on this point.

- 3.7 The appellant alleged that the approach of the Appraisal Committee to the assessment of risk in patients with osteoporosis is arbitrary and therefore perverse.

The arguments and limitations in assessing multiple risk factors had already been rehearsed. The Panel were satisfied that the Committee had considered all risk factors they were required to do by the scope, with the exception of corticosteroid therapy, which was initially considered but which expert advice counselled should be considered separately. The Panel recognised that assessing the impact of each and accumulative risk factors was a difficult area, and that the Committee had acted reasonably with the evidence placed before it.

The Panel accordingly dismissed the appeal on this point.

- 3.8 The appellant alleged that the Appraisal Committee's conclusion that raloxifene is not as effective as etidronate is perverse in the light of the evidence.

The Panel heard from the Committee that evidence base for the two technologies was different, and although RCTs were the 'gold standard', the sum of the evidence including observational studies, clinical and patient experts, justified the conclusion that 'raloxifene was not as effective as bisphosphonates'. The Panel concluded that such a conclusion could not be described as perverse.

The Panel accordingly dismissed the appeal on this point.

- 3.9 The appellant alleged that the refusal of the Appraisal Committee to rely upon the incidence of breast cancer found in clinical practice is perverse.

The Panel advised the appellant that it was for the Appraisal Committee, not the Panel, finely to weigh up the different economic modelling assumptions. An explanation of their thinking is outlined in FAD paragraph 4.2.7.5. There is no perversity in the Committee's consideration of the three models.

The Panel accordingly dismissed the appeal on this point.

4. Appeal ground three: That the institute has exceeded its powers

No grounds were raised.

5. Conclusions

The Appeal Panel having dismissed all points of appeal raised, this appeal is dismissed. The Panel recommends that the FAD should be passed to the Guidance Executive for publication in the usual way, but that the Guidance Executive should consider and act upon the recommendations at paragraphs 2.4, 2.8 and 3.6 above before doing so.