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Mr Mark Taylor
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22 August, 2007
Sent by email only

Dear Mr Taylor

Joint appeal by the National Osteoporosis Society, the Society for Endocrinology, the British Society for Rheumatology and the Bone Research Society regarding the NICE Final Appraisal Determinations:
Primary prevention of osteoporotic fragility fractures in post menopausal women;
and
Secondary prevention of osteoporotic fragility fractures in post menopausal women.

Thank you for your letter dated 15 August 2007 in which you notify us of your preliminary views with respect to the appeal points set out in our letter of 9 July 2007. We provide below our further submissions for your consideration, before you form a final view with respect to the admissibility of our points of appeal. As requested, we also confirm your assessment as to the particular FAD, to which each of our points of appeal relates.

Point 1.1

We confirm that this point of appeal relates to both FADs under consideration.

Your comments with respect to our point of appeal are noted.

Point 1.2

We confirm that this point of appeal relates to the FAD for primary prevention of osteoporotic fractures.

At point 1.2 of our appeal letter we raise the fact that the FAD for primary prevention appears to have disregarded the principles laid out in the Institute's document *"Social Values Judgments"*. You have expressed the preliminary view that this point of appeal may not validly be advanced under Ground 1 of NICE's procedures, but should instead proceed under Ground 2. However, you comment, *"depending on the facts of any case, it might be procedurally unfair (if, for example, you were led to believe that certain matters would be relevant and taken into account, which were not in fact considered), but this would need to be shown to be arguable."* This is of course precisely the situation that has arisen in relation to the Appraisal Committee's failure to take into account the principles set out by the

Institute's Citizens Council in "Social Values Judgments", when preparing the FAD for primary prevention of osteoporosis. NICE has established the Citizens Council in order to provide advice to the Institute on the approach to be followed and matters to be considered when undertaking technology appraisals. In these circumstances, stakeholders have a legitimate expectation that the advice provided by the Citizens Council will be taken into account by the Appraisal Committee when formulating its guidance. Indeed the judgment of the Court on R ota Eisa v. NICE included reference to the "Social Values Judgments" suggesting that it too considered this document to be of importance.

This is clearly a matter of procedural fairness and we believe that it should properly be considered under Ground 1 of our appeal.

Point 1.3

We confirm that this point of appeal relates to both FADs under consideration.

Point 1.3 of our letter of appeal concerns the lack of transparency in their appraisal, as a result of NICE's refusal to disclose a live version of the economic model relied upon by the Appraisal Committee. You have expressed the preliminary view that, in light of the judgment of the Court in R ota Eisai v. NICE, this is not an arguable appeal point. We respectfully disagree. While the judge found, in the context of the Alzheimer's disease treatments appraisal, that it was not unfair for the Institute to have refused to disclose a live version of the economic model relied on for the purposes of the guidance prepared in that case, substantial weight was placed upon the circumstances of that particular appraisal. We believe that it is therefore necessary to consider each case on its own merits and it is not appropriate to extrapolate the findings of the judge in the Eisai case, to the circumstances of the appraisals of osteoporosis treatments. In this context the following matters are also material and should be taken into account when considering our appeal:

- We note that in reaching her finding that NICE did not, as a matter of fairness, require to disclose to consultees in the Alzheimer's disease treatments appraisal, the live version of the economic model relied upon by the Appraisal Committee, the judge placed reliance upon NICE's evidence that no consultee in any other appraisal had requested access to this information. To that extent, the judge's finding was based on a misapprehension; consultees in other appraisals had requested disclosure of such information, including ourselves in 2006 in the context of these appraisals of osteoporosis treatments.

- It is clear that, following the Alzheimer's disease treatments appraisal, there has been an increasing call for transparency in relation to NICE appraisals, as demonstrated by the evidence received by the current House of Commons Health Select Committee, reviewing NICE. Specifically, many witnesses have expressed the view that there should be disclosure of live versions of the health economic model that form the basis for NICE's conclusions.

- In the WHO review of NICE entitled "Technology Appraisal Programme of the National Institute for Clinical Excellence" it was stated that "*allowing confidential material as part of the decision-making process obscures the transparency of decisions and possibly jeopardises the quality of the NICE assessment process..... the commitment of NICE to transparency and public accountability should override the confidentiality issues and make it possible for decision-making to become even more transparent and open to scrutiny*". This report was welcomed by NICE, but the points raised do not appear to have been considered in the case of these appraisals.

- A fundamental principle in science is that nothing is accepted as established until it has undergone the peer review process and has been published in full and sufficient details to allow a skilled colleague working elsewhere to reproduce the experiment and to verify the results for themselves. The details published by NICE have not allowed consultees

to do this. Our concern is that the appraisal process is done fairly and transparently to ensure that patients benefit from the conclusions.

Therefore, we believe it is incumbent upon the Institute to consider whether, as a matter of fairness, it should have disclosed a live version of the economic model based on the particular circumstances of these appraisals and the call for heightened transparency.

Point 1.4

We confirm that this point of appeal relates to both FADs under consideration.

Your comments in relation to this point of appeal are noted.

Point 1.5

We confirm that this point of appeal relates to both FADs under consideration.

At point 1.5, we have raised the fact that NICE appears to have adopted an inconsistent approach when considering the appraisals of osteoporosis treatments to that adopted in other cases. However, you have expressed the preliminary view that this point of appeal should be advanced under Ground 2, perversity, rather than under Ground 1, procedural unfairness.

We agree, as indicated in our letter of appeal, that an inconsistent approach suggests arbitrariness, and is therefore indicative of perversity. However, we also believe that inconsistency is contrary to the requirement for equality of treatment which is a fundamental requirement of a fair procedure and properly brought under Ground 1.

Point 1.6

We confirm that this point of appeal relates to the FAD for primary prevention of osteoporotic fractures.

Point 1.6 of our appeal letter raises the issue that no explanation has been provided for the way in which clinical risk factors, used to identify patients at highest risk of fractures, have been categorised. In your letter, you express the preliminary view that this matter should be considered under Ground 2, rather than Ground 1.

While you have not provided any reasons in your letter, to explain your preliminary view, we respectfully disagree. Our point of appeal relates to the lack of transparency in relation to the conclusions reached by the Appraisal Committee. The requirement for transparency is a matter of procedural fairness and, while it is possible that after reasons have been provided (or if it is confirmed that the Appraisal Committee had no reasons for its conclusion), then an appeal could be pursued on the grounds of perversity, in the absence of adequate reasons or explanation, an appeal is properly brought under Ground 1.

Point 1.7

We confirm that this point of appeal relates to the FAD for primary prevention of osteoporotic fractures.

At point 1.7, our appeal is based on the fact that the Appraisal Committee has failed (a) to calculate ICERs in respect of primary prevention of osteoporosis on the basis that, it states, these would exceed £20,000; and (b) to explain its reasons for imposing a rigid threshold of £20,000 without reference to the factors identified in NICE's Guide to the Methods of Technology Appraisal. You have expressed the preliminary view that this point of appeal is

not admissible. You provide two reasons for this preliminary conclusion, each of which we address below:

- Firstly, while you do not address this issue in your letter, we believe it is incumbent on the Institute, as a matter of procedural fairness, to form a view as to the appropriate ICER values for a technology under consideration particularly where, as in this case, it seems likely that the ICER values will fall within a range frequently recommended by the Institute, as representing a cost-effective use of NHS resources. In circumstances where the Appraisal Committee has failed to form a view as to the ICER value for a particular technology, it has not placed itself in a position properly to consider whether a recommendation is appropriate. This is procedurally unfair.

- We are surprised by your suggestion that a failure by NICE to follow the procedures set out in the Guide to the Methods of Technology Appraisal (the Method Guide), is not a valid ground for appeal. It is self evident, that a consultee is entitled to rely upon any procedural guides issued by the Institute as describing the way in which an appraisal will be conducted and a failure to follow the methods described is clear evidence of procedural unfairness.

- You have suggested that the sections of the Methods Guide to which we refer, require only that the Institute justifies recommendations where the ICER exceeds £20,000, as an exceptional case. However, in order for the Appraisal Committee to decide whether or not a technology is an exceptional case, it must consider the factors as described in the Methods Guide. If it does not consider the factors listed, it has not adequately considered the technology under consideration, contrary to NICE's own procedures. In this case, there is no indication that the Institute has complied with its obligations under its own procedures in this context.

Point 1.8

We confirm that this point of appeal relates to both FADs under consideration.

At point 1.8 of our appeal, we raise the fact that the Appraisal Committee appears to have set different cost effectiveness thresholds in respect of use of osteoporosis treatments for primary and secondary prevention of osteoporotic fractures. In your letter, you express the preliminary view that this point of appeal should proceed under ground 2, perversity, rather than ground 1, procedural unfairness. No explanation for your view is provided, although you say that we will need to satisfy the appeal panel that the appraisals we refer to are truly comparable, such that consistent treatment can be said to be a requirement.

With respect, we find your reasoning difficult to follow. Our point of appeal relates to the fact that the basis for the cost effectiveness thresholds seemingly set by the Appraisal Committee, in relation to these two appraisals, lack transparency. We simply do not understand how the Appraisal Committee has decided that the figure of £20,000 per QALY should apply to the appraisal for primary prevention and the figure of £30,000 per QALY should apply to the appraisal for secondary prevention; it is unclear why different ICER thresholds should apply to the different appraisals. As indicated above, lack of transparency is unacceptable as a matter of procedural fairness and our appeal is properly brought under Ground 1. In this context, we do not believe it is a matter for consultees to be required to justify that consistent treatment is appropriate, but rather that the Appraisal Committee should explain why it has applied different cost effectiveness thresholds. Indeed the report published by the WHO when they reviewed NICE in 2003, stated that *"As part of the process of articulating the criteria for decision-making, NICE must resolve the confusion related to the use of a value-for money threshold. If a threshold is to be used as the basis for recommendations, it needs to be specified and justified for reasons of transparency"*. Such reasoning is wholly lacking in this case.

Point 1.9

We confirm that this point of appeal relates to both FADs under consideration.

Point 1.9 relates to the fact that NICE has chosen to recommend only a single product for use in this therapeutic area, irrespective of the fact that it may not be taken by certain patients with the condition under consideration and that in others it will not produce the desired benefit. The sole reason for the decision appears to be that the product is now available in a generic formulation and therefore at reduced cost and appears to disregard the fact that the ICER values for other osteoporosis treatments would seem likely to fall within the range frequently recommended by NICE in other appraisals. In your letter, you express the preliminary view that our point of appeal provides no evidence that the Guidance will limit innovation and that, accordingly, you are not minded to conclude that this point of appeal is admissible.

Osteoporosis treatments are often difficult to take and can cause side effects and the development of new treatments that overcome these issues is of paramount importance to patients. Furthermore the development of new treatments which act through different mechanisms will result in the improvement of care for people with osteoporosis.

We respectfully suggest that the approach followed in your letter, exceeds the remit of the initial filtering process envisaged as part of NICE's procedures, but rather seeks to adjudicate upon the substantive merits of the issue advanced in our letter of appeal. It is self evident that the strategy we describe above, which excludes newer products from recommendation by NICE will discourage innovation in developments of additional treatments for osteoporosis. We believe that the lack of innovation that is likely to result from NICE's strategy in the context of this appraisal is a matter of real concern, is contrary to NICE's own procedures and that we should be permitted to raise this important matter at the Appeal Hearing.

Point 2.1

We would like to note that this point of appeal relates to both FADs and not just to the FAD for the secondary prevention of osteoporotic fractures.

Your comments in relation to this point of appeal are noted.

Point 2.2

We confirm that this point of appeal relates to both FADs under consideration.

At point 2.2, we appeal in relation to the fact that the current assessment of cost effectiveness set out in the FAD is already out of date because it is based on a price for alendronate substantially in excess of that set out in the current Drug Tariff. You express the preliminary view that the Institute must be allowed to take a point in time for its calculations and to produce guidance on that basis (even if this means its Guidance will be out of date at the time of issue) and that, accordingly, our point of appeal should not be permitted to proceed.

Your preliminary conclusions are a matter of substantial concern to us. It is self evident that any assessment of cost effectiveness will be substantially influenced by the price of the product under consideration and it is futile for NICE to issue guidance to the NHS on the use of a product, based on a conclusion that is clearly incorrect at the date it is issued. In circumstances where NICE's guidance will determine whether or not patients are permitted to receive NHS treatment with a product under consideration, this point of appeal should not be dismissed as a technicality.

It is significant that, in our response to recent ACDs issued in these appraisals, we pointed out to NICE that the price for alendronate, which formed the basis for the assessment of cost effectiveness, was already out of date at that stage and that further decreases in price were expected shortly. It is therefore clear, that, on any view, the Appraisal Committee should have required a review of cost effectiveness, based on the price for alendronate that was current at the date the FAD was issued and should, in our view, have made enquiries as to when a further price reduction was anticipated, to ensure that the Guidance was accurate at the date of issue. The issue of Guidance, based on out of date pricing figures, is meaningless and therefore perverse. Furthermore, we believe that such a marked decrease in price will significantly impact on cost effectiveness meaning that patient care will be affected, resulting in women at a high risk of experiencing a fracture being denied access to cost-effective treatments.

Point 3.1

We confirm that this point of appeal relates to both FADs under consideration.

Your comments in relation to our point of appeal are noted.

Point 3.2

We confirm that this point of appeal relates to the FAD for primary prevention of osteoporotic fractures.

Your comments in relation to our point of appeal are noted.

Point 3.3

We confirm that this point of appeal relates to both FADs under consideration.

Your comments in relation to our point of appeal are noted.

Thank you for considering these additional submissions in relation to our points of appeal and we look forward to receiving your final determination in respect of their admissibility.

Yours faithfully,

[redacted]

Policy and Information Officer
National Osteoporosis Society

For and on behalf of the National Osteoporosis Society, the Society for Endocrinology, the British Society for Rheumatology and the Bone Research Society