National Institute for Health and Clinical Excellence

Sanofi-Aventis UK
On behalf of the Alliance for Better Bone Health
One Onslow Street
Guildford, GU1 4YS

Tuesday 4th September 2007 Sent by email



FAD Primary and Secondary prevention of osteoporotic fragility fractures in postmenopausal women

Thank you for your letters dated 9 July 2007. This letter is my preliminary assessment of the validity of your appeal points, as required by NICE's appeal process.

As the paragraphs of your letters are not numbered, I will adopt the numbering of your appeal points give in the "Executive summary" on page one of your letters. Following the conclusion of this initial scrutiny, it would greatly assist the appeal panel if you would resubmit your valid appeal points in a letter with numbers paragraphs, or at least with each separate point given a numbered heading.

Ground one point one (Primary and secondary)

A valid appeal point.

Ground one point two (Primary and Secondary)

Essentially a valid ground one appeal point, although it seems to me that the second bullet point under this heading, on page 2 of your letter, would be better considered as a ground two appeal point. As it stands it does not seem to me that this relates to a failure to follow published procedures, nor can I see any procedural unfairness.

Ground two point one and point two (Primary and Secondary)

Valid appeal points

Ground two point three (Secondary only)

I do not think this is a valid appeal point of itself. The section you refer to describes the technologies appraised. It is not guidance, nor is it evidence or discussion of evidence leading to the guidance. If the paragraph cited is mistaken, or misleadingly incomplete, then it seems to me that it could be evidence of perversity if it suggests the committee misunderstood some relevant aspect of the technology), or, if it might materially mislead readers of the guidance, it might be perverse in its own right. But if it is merely a summary of the technology under appraisal then, even if inaccurate or

incomplete, I would struggle to see how that could render the guidance itself perverse. At present I would not be minded to allow the appeal point to proceed.

As an appeal will take place in any event, the Institute will contact you to make the necessary arrangements. If you wish to make any further submissions on your point on ground one point two or ground two point three, I would be happy to consider them before reaching a final decision on those issues. I would be grateful for any such reply within twenty one days of this letter.

Yours sincerely

Mark Taylor Chair, Appeal Panel