

Servier laboratories Limited Gallions, Wexham Springs Framewood Road Wexham Slough SL36RJ

7 September 2007 Sent by email

Dear Sirs.

FAD Primary prevention of osteoporotic fragility fractures in postmenopausal women

FAD Secondary prevention of osteoporotic fragility fractures in postmenopausal women

Thank you for your letter dated 5 September 2007. This letter is my final assessment of the validity of your appeal points, as required by NICE's appeal process.

Thank you for renumbering your appeal points. I will adopt the amended numbering in this letter. To assist any other reader of this letter in following our correspondence I include in brackets the older numbering.

Para 1.1 (old para 3)

I note this has been moved to ground one as suggested. I agree it is a valid appeal point under that ground.

Para 1.2 (old para 4)

Previously accepted as valid

Para 1.3 (old para 5)

I still cannot see a breach of procedure or unfairness here (although the same point is a valid ground of appeal under ground two) and I do not agree this point should be considered under this ground.

Para 1.4 (old para 7)

I am still doubtful that the reference to the Social Values Judgement will add to the validity of this point, but, be that as it may, I agree that the essential complaint that new evidence was not addressed should be considered by the appeal panel.

Para 1.5 (old para 8)

Thank you for your further elaboration of this point. I regard the Eisai judgement as determinative on the issue that there is no need for release of an executable model, and that NICE's procedures surrounding the release of models are in principle fair. I

do not agree that any generic challenge on those grounds may be brought. But I agree that the question of whether as a matter of fact in this case you were sufficiently aware of the inputs and assumptions in the model to make an intelligent response is a valid ground of appeal.

Para 1.6 (old para 9)

Previously accepted as valid

Para 2.1 (old para 1, firts part)

I previously suggested this point should be considered, but only on the basis that it was perverse not to conclude that exceptional circumstances applied such that the study to which you refer should be considered in evidence. That is still my view and I confirm that the appeal point should be considered on that basis.

Para 2.2 (old para 1, second part)

As now presented, this point does seem to be distinct from para 2.1, and should be considered as a valid ground two point.

Para 2.3 (old para 2)

Previously accepted as valid.

Para 3.1 (old para 10)

Previously accepted as valid

Para 3.2 (end of old para 7)

I agree that these points may proceed, but would remind you to address the issue of whether article 8 is engaged. I would also draw your attention to NICE's positive equalities duties, and invite you to address the appeal panel if you consider any of those to be relevant.

Yours sincerely

Mark Taylor Chair, Appeal Panel