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29th August 2006

Dr Carole Longson
Appraisal Programme Director
National Institute for Health and Clinical Excellence
MidCity Place
71 High Holborn
London
WC1V 6NA

Dear Dr Longson

Re: **Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women** and **Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women.**

Thank you for sending through the latest report from the DSU containing their new analyses for the above Appraisal and inviting our comments.

We have carefully reviewed the new analysis and have the following comments:

1) We are dissatisfied that this analysis does not allow us to see what the cost per QALY values actually were for raloxifene. A threshold of >£20K is applied as "a rule" and therefore we are unable to see the actual values. These may have been below £30K, for example, in which case further discussion on clinical and economic value would be warranted.

2) The application of a £20K threshold for the analysis is clearly applied to restrict patient access and we believe this to be inappropriate, in that this pre-judges the appraisal committee's discussions on drawing up guidelines based on full consideration of economic and clinical value.

3) If 5.1 and 5.2 were calculated using £30K as a threshold, the values obtained would enable a range of BMDs to be derived which would allow the Appraisal committee to select from these and result in greater clinical applicability (e.g. Treatment may still be cost effective at lower BMDs.)

   A threshold of £30K would improve access to all medicines assessed, and result in improved patient choice.

   This possibility has not been explored in this analysis.

4) Table 7 on page 36 presents no results for raloxifene.

5) We do not know from the information presented whether the values used for raloxifene did, or did not include the breast cancer benefit. In light of the recently published STAR trial (*Vogel et al. Effects of Tamoxifen vs Raloxifene on the Risk of Developing Invasive Breast Cancer and Other Disease Outcomes*. *JAMA 2006; 295: 2727-2741*) we believe

this remains an important issue. We continue to assert that the appropriate economic analyses should take full account of the benefits accruing from reduction in breast cancer risk. The DSU analysis is seriously flawed if this is not the case. The appraisal committee has previously exercised its right to draw up guidance which discounts this important benefit, and may do so again, but the formal analysis should show the full benefit.

6) The results presented in this analyses support our previous assertions that teriparatide is cost-effective in women of a younger age with severe osteoporosis and we hope that the resulting ACD will clearly reflect this.

Yours sincerely