

29 August 2006

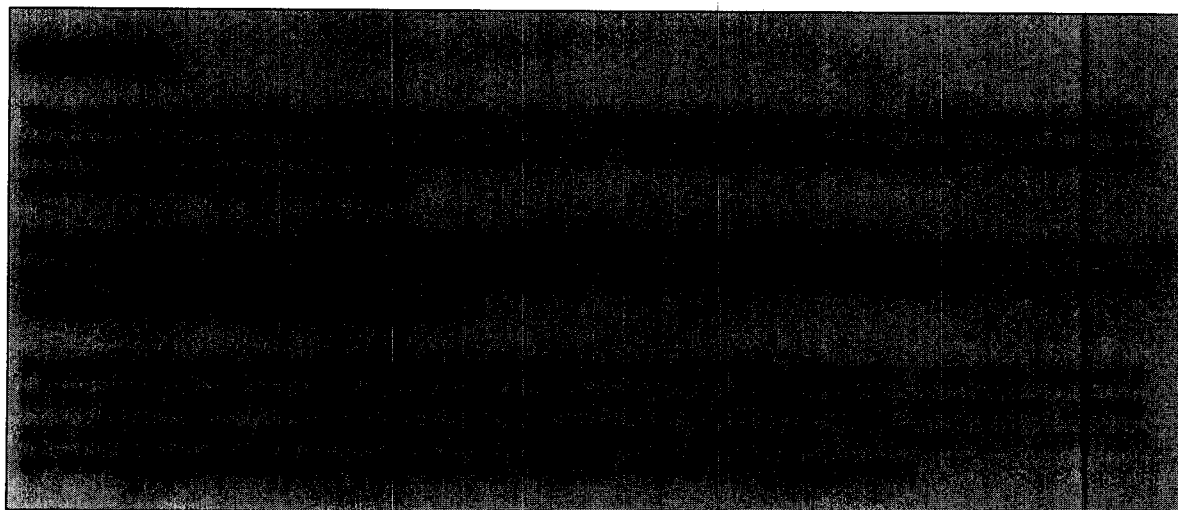


Dr Carole Longson
Director
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National Institute for Health and Clinical Excellence
MidCity Place
71 High Holborn
London WC1V 6NA

Dear Carole

DSU analysis: appraisals of technologies for the primary and secondary prevention of osteoporotic fragility fractures in postmenopausal women

Thank you for the above report. Please see below comments from the Alliance for Better Bone Health on behalf of sanofi-aventis and Procter & Gamble (The Alliance).



Presentation

In our consideration of the report, we found that not enough data are presented to allow the reader to understand how results were reached or how they should be interpreted.

The Alliance believes that elements of the report will require clarification before the Appraisal Committee and consultees and commentators can make an informed assessment, including:

- Revision of the focus from modelling patient identification strategies to primary/secondary prevention;
- Clarification of the contribution of specific risk factors to the model results;
- Interpretation of these findings in the context of the previous analyses on primary / secondary prevention.

Consideration

It is not clear how the DSU report impacts on the existing evidence that the Committee has previously reviewed or the Committee's previous recommendations that, in choosing which bisphosphonate to use, clinicians and patients need to balance the drug's overall proven effectiveness profile against tolerability and adverse effects in individual patients.

We understand that the authors of the DSU report will be invited to attend the Appraisal Committee meeting on 6 September and respond verbally to comments made during the consultation. The Alliance would be grateful for further details and clarification of how their responses will be presented or documented as part of the subsequent consultation on the ACD.

We would like to make the Institute aware that new data has become available that the Committee may wish to consider. Please note that this information is currently [REDACTED]:

[REDACTED]

Yours sincerely

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]