Nancy tait OED

From: Nancy Tait [redacted]
Sent: 26 April 2006 15:40
To: Emily Marschke
Subject: Pemetrexed Appraisal

FROM OEDA - OCCUPATIONAL AND ENVIRONMENTAL DISEASES ASSOCIATION

Health technology Appraisal
Pemetrexed disodium for the treatment of malignant pleural mesothelioma

a) Appraisal Consultation Document

b) Evaluation Report

Thank you for sending me the Documents.

Having studied them carefully, I am sending you a copy of OEDA's comments, e.mailed 7 February 2006 to Cathryn Fuller.

Clearly, more research to find an effective treatment for mesothelioma is needed urgently.

NT/MW February 2006

Dr Carole Longson
Director, Centre for Health Technology Evaluation National Institute for Health and Clinical Excellence Mid City Place
71 High Holborn
London WC1V 6NA

Health Technology Appraisal
Pemetrexed disodium for the treatment of malignant pleural mesothelioma

Thank you for inviting me to comment on the LRIG assessment report on malignant pleural mesothelioma.

I have been aware of the disease since my husband, a Post Office Engineer, died from MPM in June 1968. He worked in and visited Telephone Exchanges and Repeater Stations but had not himself handled asbestos. The exposure responsible was identified as work in the Defence Communications HQ, Whitehall. Each sector was lined with amosite insulation board. This was all cut in the PO area while engineers were on duty.
Mesothelioma was diagnosed in June 1967; the pleura was removed November 1967.

From 1981 I offered mesothelioma patients at Hackney Hospital, advice on special benefits available. This soon became a nationwide service so that I have met, telephoned and/or corresponded with several thousand mesothelioma patients. I have called on both experiences to provide these comments.

1) The prediction that mesothelioma would not occur after the year 2000 has proved false.

Patients are distressed if told no treatment is available; morale improves if treatment is offered. But pemetrexed therapy is suitable for only a relatively small number of MPM patients. Research and funding to find and provide effective treatment for all mesothelioma patients is needed urgently.

2) Randomised controlled clinical trials may be regarded as essential for assessing clinical efficacy of new drugs but are not appropriate for mesothelioma patients whose life expectancy is so short that they need to make an informed choice; do they want treatment? If so the benefits and toxicities of treatments available should be explained to them. The choice should be theirs. LRLG appears to share this view, They conclude:

Any decision to use pemetrexed plus cisplatin in an individual patient needs to be in full collaboration with that patient, against a background of high quality palliative care services. The patient needs to be well informed of the benefits and toxicities of the regimen. Much more research is needed into the optimum chemotherapy for these patients, and a clear definition of what constitutes best supportive care. (page 86)

3) Survival time for those treated with pemetrexed plus cisplatin is not significantly longer than that of those who receive no chemotherapy. Quality of life may be poor: it is recognised that when pemetrexed is used the incidence of severe toxicity is high. (page 85)

4) Quality of life is important. I am concerned that I have been able to obtain only limited information on the criteria to be used when assessing Quality of Life. It appears that it is often ignored or only poorly assessed.

5) The cost of pemetrexed is high. I agree with the Eli Lilly conclusion that pemetrexed plus cisplatin does not fall within the conventional range of cost-effectiveness. While they believe that the therapy should be given special consideration owing to the lack of any other proven alternative to supportive care, I feel that there should in addition be funding to find treatment that will benefit all mesothelioma patients. For example, early diagnosis would benefit all.

6) I am concerned to read that Eli Lilly has granted to the Assessment Group only limited access to selected individual patient date (IPD) (page 75). I find this worrying and unacceptable.

7) There is a suggestion that costs would be cut if pemetrexed were to be made available in smaller vials, yet 100 mg vials will not be available until 2008 or later (page 75). This seems to be unreasonably delayed. Can Eli Lilly not make other additional cost savings?

8) The assessors recognise (page 23) that because this was a single blind trial, bias may have been introduced.

9) How many more patients have refused to participate in pemetrexed trials when told that they could be 'randomly' i.e. arbitrarily allocated to a group denied any treatment?

Conclusion

Victim support groups are pressing for the use of pemetrexed. OEDA agrees that earlier diagnosis and more effective treatment are needed but the information made available in this Assessment Report suggests that relatively few will benefit from the introduction of pemetrexed and their survival time will be only marginally increased.

More effective treatments are needed. See 1.

More attention should be paid to the patients Quality of Life. See 4.

Can random allocation to a study group be justified? See 9.

Nancy tait OED

Nancy Tait MBE Hon Duniv

--

Delivered via MessageLabs
