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Dear Emily

Health Technology Appraisal – Pemetrexed disodium fir the treatment of malignant pleural mesothelioma – Appraisal Consultation Document

Thank you for the opportunity to comment on the appraisal consultation document for the above health technology appraisal.

The Department of Health have no specific comments to make on the consultation document.

However, we have been asked to pass on some comments from a number of clinicians and charities who advises the Department of Health on this condition. I have attached these comments at Annex A but I am sure you will have already received these comments directly.

Yours sincerely

Simon Reeve
Head of Clinical and Cost Effectiveness

Annex A

Comments made by Stakeholder interests.

- there are few choices in the treatment of mesothelioma and little research has been done to find new treatments. For the first time patients felt that there was some hope of being offered treatment when this came along. The trial results have shown that the use of this drug prolongs life. This may only be by 3-5 months but if the total amount of time left to a person from diagnosis is averaging 9 months then this is an important extra period of time in which much can be achieved.

- It is hard to quantify the effect that the "banning" this treatment will have on mesothelioma sufferers and their families but there is real anger among patients and their families about the lack of emphasis placed on the treatment of mesothelioma. This draft guidance, if confirmed by NICE, will only confirm people's fears that they have been forgotten and their lives are of less value than those of people with other cancers which have a higher profile in the media.

- The way the draft reads on page 14 para 4.3.7 indicates that performance and improvement is not the key – economics is.

- This is the only licensed treatment for mesothelioma. Whilst it is accepted that the evidence could be better, clinicians who have used the pemetrexed/cisplatin combination in appropriate patients have seen clinical benefit and would want to be able to consider it for the treatment of patients with good performance status but troublesome symptoms.

- agree that the evidence base for the use of Pemetrexed is far from ideal and that there are no data against best supportive care but that is also true for other chemotherapy regimes in use by many oncologists across the UK.

- there are no trials including Pemetrexed available to the generality of clinicians in this field in the UK, therefore NICE's conclusion will, in effect, be banning the use of Pemetrexed in mesothelioma in the UK on the NHS unless the Clinical Trials Advisory & Awards Committee can be persuaded to urgently set up and fund a trial. Even if a trial is established, there will be implications for patients who do not consent to randomisation into a trial and for whom a clinician may consider chemotherapy may be appropriate

- concern that stating that pemetrexed may only be allowed within clinical trials is not ethical (point 1.10 of the Declaration of Helsinki (1964):'*When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in dependent relationship to him or her or* ***may consent under duress*****.....'). If patients are aware that the only way of receiving the licensed therapy for their disease is within a trial, one might consider that the NICE guidance comes close to introducing 'consent under duress'.

- Plea for NICE to recommend that, wherever possible, patients should receive chemotherapy for mesothelioma in the context of a clinical trial, but that consideration can also be given to prescribing pemetrexed (by a specialist oncologist) where a trial is not available or where a patient does not consent to take part in a trial but has good performance status (status 0 and 1).