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HO/HTA Strategy

Medical and Product Information:

21st March 2007

Mr Mark Taylor
The National Institute for Health
And Clinical Excellence
MidCity Place
71 High Holborn
London
WC1V 6NA

Dear Mr Taylor

Appeal in relation to the FAD for pemetrexed disodium for the treatment of non-small cell lung cancer

Thank you for your letter of 7 March 2007 in which you provide your initial views regarding the admissibility of Lilly's points of appeal, as set out in our letter of 1 March 2007. Our further submissions in response to the matters raised in your letter are set out below, for your consideration, before you reach a final decision with respect to the admissibility of our points of appeal.

We confirm that our letter of 1 March 2007 contained all of the grounds upon which Lilly wishes to appeal. The reference to points of appeal under ground 2 in our letter of appeal, was included in error.

We note that you agree the points of appeal raised in our letter under ground 1 are valid. You express the preliminary view that Lilly's point of appeal raised under ground 3 (i.e. that the content of the FAD is inconsistent with the marketing authorisation for pemetrexed disodium) is not valid. You provide the following explanation for your conclusion: (i) you say that the FAD states the conclusions of the CHMP; and (ii) while you agree that NICE would act outside its remit if it moved into the area of product licensing, you say there is no obligation upon the Institute to accept the findings of fact of the CHMP, when it is acting within its own remit of assessing clinical and cost effectiveness.

Lilly respectfully disagrees with your preliminary conclusions with respect to our ground 3 point of appeal.

- Firstly, the fundamental conclusion of the CHMP and the basis for the marketing authorisation for pemetrexed disodium was that any clinically significant inferiority of pemetrexed to docetaxel in terms of efficacy is unlikely[1]. In these circumstances, any differences in efficacy are not relevant to NICE's appraisal. However, the Appraisal Committee has seemingly disregarded the conclusions of the CHMP with respect to

clinical significance, stating simply at paragraph 4.2 of the FAD, that pemetrexed may be less effective than docetaxel.

- Secondly, while the Institute is entitled to form its own view as to the clinical and cost effectiveness of the technology under consideration, what it has done in paragraph 4.2 of the FAD is to express a view in relation to efficacy (i.e. precisely the same issue considered by the regulators, rather than clinical or cost effectiveness) which undermines the marketing authorisation for the product.

Therefore NICE has exceeded its own powers and Lilly's point of appeal is properly brought under ground 3.

We look forward to receiving your final decision with respect to the admissibility of our appeal.

Yours faithfully.

Manager, UK HTA & Health Outcomes

1. European Public Assessment Report (EPAR) on pemetrexed, page 50, available from: http://www.emea.europa.eu/humandocs/PDFs/EPAR/alimta/102004en6.pdf