CASES AUTH/2039/8/07 and AUTH/2040/8/07

PRIMARY CARE TRUST MEDICINES MANAGEMENT PROGRAMME DIRECTOR v BIOGEN IDEC and ELAN PHARMA

Letter about Tysabri

The medicines management programme director at a primary care trust complained about a letter promoting Tysabri (natalizumab) sent by Biogen Idec. Elan Pharma International held the marketing authorization for Tysabri and the letter included Biogen's and Elan's logos on the reverse. The complaint was taken up with both companies.

The letter, headed 'Tysabri is now recommended by [The National Institute for Health and Clinical Excellence] NICE', stated that the product had received a positive final appraisal determination from NICE. The complainant noted that whilst it was very likely that the NICE final appraisal determination would be the guidance to be issued for the NHS, this was not necessarily so. The medicine was not actually recommended for the NHS until the technology appraisal had been issued. The complainant alleged that the heading 'Tysabri is now recommended by NICE' was untrue, misleading and should be withdrawn.

The Panel considered that the heading implied that the recommendation from NICE was final which, when the letter was sent out (14 August), was not so. NICE published the relevant technology appraisal guidance eight days later (22 August). Although the first paragraph of the letter explained that Tysabri had recently received a positive final appraisal determination this did not, in the Panel's view, negate the otherwise false impression of finality given by the heading. In any event the Panel queried how many recipients would appreciate the status of a final appraisal determination.

The Panel considered that when the letter was sent the heading was untrue and misleading as alleged. Breaches of the Code were ruled.

The medicines management programme director at a primary care trust complained about a letter promoting Tysabri (natalizumab) (ref TY00-GBR-22242) sent by Biogen Idec Limited. Elan Pharma International Ltd held the marketing authorization for Tysabri and the letter included Biogen's and Elan's names in logo format on the reverse. The complaint was taken up with both companies.

COMPLAINT

The complainant noted that whilst it was very likely that the NICE final appraisal determination would be the guidance to be issued for the NHS, this was not necessarily so. Also the medicine was not actually recommended for the NHS until the technology appraisal had been issued. The complainant alleged that the heading 'Tysabri is now recommended by NICE' was untrue, misleading and should be withdrawn.

In writing to the companies the Authority drew attention to Clauses 2, 7.2, 7.4 and 9.1 of the Code.

RESPONSE

Biogen Idec and Elan noted that the letter was sent to primary care organisations to inform them of the positive final appraisal determination for natalizumab for the treatment of adults with highly active relapsing-remitting multiple sclerosis from NICE. The heading 'Tysabri is now recommended by NICE' was followed by 'We are pleased to announce that Tysabri has recently received a positive final appraisal determination from NICE. The committee acknowledge that Tysabri is a clinically and cost effective treatment for Highly Active Relapsing Remitting Multiple Sclerosis. This is defined by one or more disabling relapses in one year, and one or more gadolinium-enhancing lesions on brain magnetic resonance imaging (MRI) or a significant increase in T2 lesion load compared with a previous MRI'.

The companies submitted that the claim 'Tysabri is now recommended by NICE' was true. Section 1.1 of the final appraisal determination for natalizumab for the treatment of adults with highly active relapsing-remitting multiple sclerosis stated that:

> 'Natalizumab is recommended as an option for the treatment only of rapidly evolving severe relapsing-remitting multiple sclerosis (RES). RES is defined by two or more disabling relapses in 1 year, and one or more gadolinium-enhancing lesions on brain magnetic resonance imaging (MRI) or a significant increase in T2 lesion load compared with a previous MRI.'

The companies submitted that the claim was also not misleading. The letter cited a publicly available document and clearly indicated that the recommendation was from the NICE final appraisal determination for natalizumab. The letter did not state that Tysabri was recommended for the NHS.

The companies submitted that there was no need for the claim at issue to be withdrawn for the reasons set out above. Not only was natalizumab recommended as a treatment for highly active relapsing-remitting

multiple sclerosis in the final appraisal determination, but it had also been recommended in the NICE technology appraisal guidance 127 (Natalizumab for the treatment of adults with highly active relapsing-remitting multiple sclerosis).

The companies submitted that the letter was accurate, balanced, fair, objective and unambiguous, and that the claims therein were capable of substantiation. High standards had been maintained and the companies vehemently rejected any suggestion that the letter discredited or reduced confidence in the pharmaceutical industry. The companies denied breaches of Clauses 2, 7.2, 7.4 or 9.1.

In response to a request for further information the companies submitted that the letter at issue was sent on 14 August 2007; the final appraisal determination was published 3 July 2007 on the NICE website. The NICE Technology Appraisal Guidance 127 was issued 22 August 2007.

The companies submitted that their understanding of the status of a final appraisal determination was that following various rounds of consultations and evaluation of the available evidence, NICE issued its final recommendations in the final appraisal determination which it distributed to all consultees and commentators to the appraisal. Consultees might appeal against the final recommendations and had 15 working days from receipt of the final appraisal determination in which to do so. The final appraisal determination was placed on NICE's website 5 working days after it had been sent to the consultees and commentators. Upon expiry of the appeal period or, if an appeal was lodged, the resolution of the appeal, NICE published its guidance to the NHS. There were only three grounds upon which a consultee might appeal: NICE had failed to act fairly and in accordance with its published procedures; the final appraisal determination was perverse in the light of the evidence submitted or NICE had exceeded its powers.

PANEL RULING

The Panel considered that the letter heading, 'Tysabri is now recommended by NICE', implied that the recommendation from NICE was final which, when the letter was sent out (14 August), was not so. NICE published the relevant technology appraisal guidance eight days later (22 August). Although the first paragraph of the letter explained that Tysabri had recently received a positive final appraisal determination this did not, in the Panel's view, negate the otherwise false impression of finality given by the heading. In any event the Panel queried how many recipients would appreciate the status of a final appraisal determination.

The Panel considered that when the letter was sent the heading was untrue and misleading as alleged. Breaches of Clauses 7.2 and 7.4 were ruled. In the circumstances it did not consider that high standards had not been maintained and no breach of Clause 9.1 was ruled.

The Panel did not consider that the matter warranted a ruling of a breach of Clause 2 of the Code which was a sign of particular censure and reserved for such.

Complaint received	**24 August 2007**
Case completed	**22 October 2007**