CASE AUTH/1845/6/06

PRIMARY CARE TRUST ASSISTANT DIRECTOR OF PUBLIC HEALTH v ASTRAZENECA

Arimidex journal advertisement

An assistant director of public health at a primary care trust, complained about an advertisement for Arimidex (anastrozole), issued by AstraZeneca. Arimidex was indicated for the treatment of advanced breast cancer in postmenopausal women and as an adjuvant treatment of postmenopausal women with hormone receptor positive early invasive breast cancer. The advertisement showed a large rectangle subdivided into four smaller rectangles. Three of the smaller rectangles featured a picture of a woman and the fourth contained the claim '26% is a very big difference in breast cancer recurrence if you are that 1 in 4'.

The complainant alleged that the advertisement implied that 1 in 4 breast cancer sufferers would benefit from taking Arimidex ie the number-needed-to-treat (NNT) was 4. The complainant noted that the 26% quoted referred to the relative risk reduction seen in the ATAC study for the endpoint of time-to-recurrence. A relative risk reduction of 26% did not correspond to an NNT of 4. From the figures quoted in the published paper, the complainant calculated the NNT to be 59 at 3 years, 36 at 5 years, and 27 at 6 years. The complainant alleged that the advertisement was very misleading and implied that Arimidex was far more beneficial than it actually was.

The Panel noted the claim '26% is a very big difference in breast cancer recurrence if you are that 1 in 4' was asterisked to a footnote which explained that the 26% was risk reduction with Arimidex over tamoxifen in hormone receptor positive postmenopausal women. The Panel noted that the footnote thus contained information which was fundamental to understanding the claim at issue. Without reading the footnote the Panel considered that the advertisement implied that 1 in every 4 patients treated with Arimidex would not have a recurrence of their breast cancer. This was not so. The Panel considered that the advertisement was misleading as alleged. A breach of the Code was ruled.

An assistant director of public health at a primary care trust complained about an advertisement (ref ARIM 06 18600) for Arimidex (anastrozole), issued by AstraZeneca UK Limited, which had appeared in Prescriber on 19 May. Arimidex was indicated for the treatment of advanced breast cancer in postmenopausal women and as an adjuvant treatment of postmenopausal women with hormone receptor positive early invasive breast cancer. The advertisement showed a large rectangle subdivided into four smaller rectangles. Three of the smaller rectangles featured a picture of a woman and the fourth contained the claim '26% is a very big difference in breast cancer recurrence if you are that 1 in 4'.

The advertisement had variously appeared in Prescriber, the BMJ and Hospital Doctor between 5 May and 22 June 2006.

COMPLAINT

The complainant alleged that the advertisement implied that 1 in 4 breast cancer sufferers would benefit from taking Arimidex ie the number-needed-to-treat (NNT) was 4.

The complainant noted that the 26% quoted referred to the relative risk reduction seen in the ATAC study for the endpoint of time-to-recurrence. A relative risk reduction of 26% did not correspond to an NNT of 4. From the figures quoted in the published paper, the complainant calculated the NNT to be 59 at 3 years, 36 at 5 years, and 27 at 6 years. None of these was close to 4. No data was provided in the paper beyond 6 years. Time-to-recurrence was not even the primary endpoint in the ATAC study.

The complainant alleged that the advertisement was very misleading and implied that Arimidex was far more beneficial than it actually was. The advertisement should be withdrawn and a correction published, preferably quoting the true NNTs. It would be a great step forward if advertisements had to quote NNTs.

RESPONSE

AstraZeneca submitted that the advertisement was an attempt to convey the patient perspective of a statistical endpoint and the image reflected a visual representation of a relative reduction in recurrence. The claim '26% is a very big difference …' was aligned to the empty box, to show the fourth woman who might recur on tamoxifen but be saved from recurrence by Arimidex.

The claim '26% is a very big difference …' was amplified in the footnote 'ATAC shows that in hormone receptor positive postmenopausal women, Arimidex gives a 26% risk reduction over tamoxifen; this is in addition to the 47% risk reduction previously shown for tamoxifen versus placebo'. This made it quite clear that it was referring to recurrence relative to tamoxifen-treated patients. In addition the inclusion of safety information further ensured prominence of this text.

The complainant had alleged that 'A relative risk reduction of 26% did not correspond to a NNT of 4 ….a correction should be published preferably quoting the true NNTs'. AstraZeneca noted that in the context of reduction in recurrence in patients taking tamoxifen, the 26% risk reduction did equate to a NNT of 4. However, AstraZeneca noted that in the advertisement it had only included data quoted in the source reference, the ATAC Trialists' Group publication from The Lancet 2005. This reference did not contain any NNT data and indeed there were no such data in either of the previous ATAC publications,

in The Lancet 2002 and Cancer 2003. In addition, the hazard ratios from the ATAC study, rather than figures for NNT were quoted in the Arimidex summary of product characteristics (SPC).

AstraZeneca noted the complainant's comment that time to recurrence was not even a primary endpoint in the ATAC study and submitted that time to recurrence was a protocol-defined secondary endpoint of the study. It included all recurrences, new breast cancers and deaths due to breast cancer. In the treatment of early breast cancer, patients and their doctors found the prevention of recurrence, which in turn was likely to delay death from breast cancer, was hugely important and this information was what was represented.

AstraZeneca submitted that the ATAC primary endpoint of 'disease-free survival' covered not only recurrence and breast cancer death, but also death due to any cause and was also significantly in favour of Arimidex compared to tamoxifen. Death due to any cause was not a sign of the return of breast cancer and therefore not a predictor of the efficacy of breast cancer treatment. This composite endpoint would therefore be less informative to doctors when deciding on the optimal treatment for their patients.

AstraZeneca noted the complainant's allegation that the advertisement was very misleading and implied that Arimidex was far more beneficial than it actually was. AstraZeneca submitted that it had addressed the complainant's points, showing that the advertisement related to the relative risk of recurrence in patients on Arimidex compared with those given tamoxifen; that it was not appropriate to calculate NNTs from the data and that time to recurrence was a meaningful endpoint in this context. The above points demonstrated that the advertisement was not misleading and did not suggest an unrealistic benefit from prescribing Arimidex.

PANEL RULING

The Panel noted that the supplementary information to Clause 7.2 of the Code stated that in general claims should not be qualified by the use of footnotes and the like. The claim '26% is a very big difference in breast cancer recurrence if you are that 1 in 4' was asterisked to a footnote which explained that the 26% was risk reduction with Arimidex over tamoxifen in hormone receptor positive postmenopausal women. The Panel noted that the footnote thus contained information which was fundamental to understanding the claim at issue. Without reading the footnote the Panel considered that the advertisement implied that 1 in every 4 patients treated with Arimidex would not have a recurrence of their breast cancer. This was not so. The Panel considered that the advertisement was misleading as alleged. A breach of Clause 7.2 of the Code was ruled.

Complaint received **7 June 2006**

Case completed **28 July 2006**