CASE AUTH/2134/6/08

PHARMACIST v JANSSEN-CILAG

Lyrinel XL journal

A pharmacist complained about a Janssen-Cilag advertisement for Lyrinel XL (oxybutynin hydrochloride).

The advertisement was headed 'Gets our vote' followed by details from Diokno *et al* 2002 that '1,067 patients enrolled in an open-label study of extended-release oxybutynin. Three quarters of these (795) remained in the study by 3 months, of which 88% indicated that they would recommend extended-release oxybutynin to others.' Beneath the claim was an illustration of an audience most of which were holding up a card with a photograph of a camel on it. One woman in the front row was not holding up her card. The complainant stated that in the illustration there were 24 clearly distinguishable cards with only one woman clearly not holding her card up. This equated to 4% rather than 12% who would not recommend this product before taking into account any drop out rate! The complainant alleged that the pictorial representation misrepresented the data presented at the top of the page.

The Panel did not consider that the illustration was a fair reflection of the total data. The patients who had discontinued by three months were not represented at all. The illustration implied that only 4% (1/24) of patients would not recommend the product to others and this was not so. The illustration together with the prominent heading 'Gets our vote' implied that almost everyone who took Lyrinel XL would be happy to stay on it. This was not so. Diokno *et al* reported that after 3 months 25% (272) of patients discontinued therapy mainly due to adverse events (166) or lack of efficacy (52). Those who stayed on therapy after 3 months were thus a selected group of patients who could tolerate therapy and for whom it was effective. Even out of this group 12% (95) would not recommend the product to others. In effect, after 3 months' therapy approximately 29% of patients who originally started therapy (313/1067) would presumably not recommend the product to others. This was not consistent with the illustration which was misleading and exaggerated. The Panel did not consider that the inclusion of some of the data from the study as a heading to the advertisement was sufficient to negate the effect of the illustration. The Panel ruled breaches of the Code.

A pharmacist complained about an advertisement (ref LYR/08-0036) for Lyrinel XL (oxybutynin hydrochloride) placed by Janssen-Cilag Ltd in GP, 6 June. The product was indicated in adults for the symptomatic treatment of urge incontinence and/or increased urinary frequency associated with urgency as may occur in patients with unstable bladder. In children over six years of age Lyrinel could be used for the symptomatic treatment of detrusor hyperreflexia secondary to a neurogenic condition.

The advertisement was headed 'Gets our vote' followed by details from Diokno *et al* 2002 that '1,067 patients enrolled in an open-label study of extended-release oxybutynin. Three quarters of these (795) remained in the study by 3 months, of which 88% indicated that they would recommend extended-release oxybutynin to others.' Beneath the claim was an illustration of an audience most of which were holding up a card with a photograph of a camel on it. One woman in the front row was not holding up her card.

COMPLAINT

The complainant stated that in the illustration there were 24 clearly distinguishable cards with only one woman clearly not holding her card up. This equated to 4% rather than 12% who would not recommend this product before taking into account any drop out rate!

The complainant alleged that the pictorial representation mis-represented the data presented at the top of the page.

RESPONSE

Janssen-Cilag stated that the advertisement was published in Pulse, 4 June 2008.

The heading at the top of the advertisement 'Gets our Vote' was followed by a brief synopsis of one aspect of the study involving extended release oxybutynin (Lyrinel XL). This synopsis was well substantiated by Diokno *et al*. Janssen-Cilag submitted that the picture of a group of women 'voting' for Lyrinel XL was fair and balanced and did not mislead or misrepresent the facts as stated in the text, and so was not in breach of Clauses 7.2 or 7.8 of the Code.

The synopsis in the advertisement refered to 795 patients remaining in the quoted study at 3 months. Of these 795 patients, 88% indicated they would recommend their study medication to others. The figure of 88% was clearly displayed in the strapline in large font print. In the image only 6 individuals could be clearly seen (although 24 cards could be seen to be held up).

It was not appropriate to derive a precise

percentage response based on the picture as it was not possible to discern the total number of women represented. In mathematical terms, as only the numerator (the number of visible cards) and not the denominator (the total number of women) of the fraction was known, a precise percentage could not be calculated. For this reason, the imagery could not be described as misrepresenting the data presented, especially as the study-derived figure of 88% appeared prominently within the text.

If one followed the logic of the complainant and extrapolated that the individuals seen in the imagery represented the percentage of study patients who would recommend the product, only six individuals could clearly be seen in the foreground and of these only five were holding up cards. Therefore at most only 83% of the individuals actually seen could be interpreted as voting for the product. This was a lower figure than that described in the synopsis but was consistent with a clear majority expressing satisfaction with the medication. Further of the most prominent individuals in the front row of the image (and the clear focus of the imagery), only two of the three were holding up cards (67% voting for). A deliberate decision was made to avoid the implication that all individuals would endorse the product by ensuring that one of the three most prominent individuals seen in the front row was not holding up a card. In addition there were also several distinct gaps in the background where cards had not been held up (though these individuals could not be seen themselves).

PANEL RULING

The Panel noted that the advertisement was headed with the results from Diokno *et al*. Of the 1067 patients enrolled in the open-label study three quarters (795) remained in the study by three months of whom 88% indicated that they would recommend their study medication (extended-release oxybutynin) to others. Diokno *et al* stated that of the 272 patients who discontinued therapy at 3 months, 166 did so because of adverse events, 52 for lack of efficacy and 49 for other reasons.

The illustration showed a number of people sitting in a theatre or similar. All but one were holding up a card which had on it a picture of a camel (twenty four cards in total). The one women who had not held up her card was smiling broadly.

The Panel did not consider that the illustration was a fair reflection of the total data. The patients who had discontinued by three months were not represented at all. The illustration implied that only 4% (1/24) of patients would not recommend the product to others and this was not so. The illustration together with the prominent heading 'Gets our vote' implied that almost everyone who took Lyrinel XL would be happy to stay on it. This was not so. Diokno *et al* reported that after 3 months 25% (272) of patients discontinued therapy mainly due to adverse events (166) or lack of efficacy (52). Those who stayed on therapy after 3 months were thus a selected group of patients who could tolerate therapy and for whom it was effective. Even out of this group 12% (95) would not recommend the product to others. In effect, after 3 months' therapy approximately 29% (166+52+95 = 313) of patients who originally started therapy (313/1067) would presumably not recommend the product to others. This was not consistent with the illustration which was misleading and exaggerated. The Panel did not consider that the inclusion of some of the data from the study as a heading to the advertisement was sufficient to negate the effect of the illustration. The Panel ruled a breach of Clauses 7.2 and 7.8 of the Code.

Complaint received **16 June 2008**

Case completed **2 July 2008**