CASE AUTH/1868/7/06

DOCTOR v JANSSEN-CILAG

Tramacet electronic advertisement

A doctor complained about an electronic advertisement for Tramacet (tramadol hydrochloride 37.5mg and paracetamol 325mg) issued by Janssen-Cilag. The advertisement had appeared on www.doctors.net. Tramacet was indicated for the symptomatic treatment of moderate to severe pain.

The part of the advertisement at issue was a section which compared numbers needed to treat (NNT) for Tramacet, its constituents and other step-two analgesics. The stated NNTs were: Tramacet (75/650) 2.6; co-codamol (60/600) 4.2; paracetamol (600) 4.6; tramadol (100) 4.8; tramadol (75) 5.3 and tramadol (50) 8.3. The lower the NNT the more effective the medicine.

The complainant noted that the advertisement used the Oxford league table of analgesics, comparing analgesics by NNT. This was an established tool and widely quoted in the pain literature. Tramacet had an NNT of 2.6; however the complainant alleged that co-codamol was compared at a dose which was not the most effective (60/600) nor the dose which was most commonly used (60/1000). Had the comparisons been with this higher, more commonly used dose, the NNT of co-codamol would have been 2.2 and would not have shown Tramacet in such a favourable light. Although a relatively minor transgression, this advertisement presented a distorted picture of current analgesics.

The Panel considered that by omitting the NNT data for co-codamol 60/1000 the comparison was misleading as alleged. The Panel ruled breaches of the Code as acknowledged by Janssen-Cilag.

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COMPLAINT

The complainant noted that the advertisement used the Oxford league table of analgesics, comparing analgesics by NNT. This was an established tool and widely quoted in the pain literature. Tramacet had an NNT of 2.6; however the complainant alleged that co-codamol was compared at a dose which was not the most effective (60/600) nor the dose which was most commonly used (60/1000). Had the comparisons been with this higher, more commonly used dose, the NNT of co-codamol would have been 2.2 and would not have shown Tramacet in such a favourable light. Although a relatively minor transgression, this advertisement presented a distorted picture of current analgesics.

When writing to Janssen-Cilag the Authority asked it to respond in relation to Clauses 7.2 and 7.3 of the Code.

RESPONSE

Janssen-Cilag submitted that comparison between analgesics was common, and the comparison used in the advertisement, the Oxford league table of analgesics, used NNT, which was a widely established tool quoted extensively within the literature. The method of comparison used within the advertisement was therefore accepted as suitable, by both the complainant and Janssen-Cilag.

The focus was on the comparison between Tramacet (37.5 mg tramadol and 325mg paracetamol) and co-codamol 60/600 (codeine phosphate, paracetamol). In the case of 60/600, this represented two tablets of co-codamol at strength 30/300 ie 30mg codeine phosphate and 300mg paracetamol per tablet.

Janssen-Cilag noted the complainant's view that the most effective dose of co-codamol and also the most commonly used dose in the UK was 60/1000 ie two tablets each containing 30mg codeine phosphate combined and 500mg paracetamol. The NNT for co-codamol 60/600 (used in the advertisement) was 4.2 and that for co-codamol 60/1000 was 2.2. Tramacet by comparison was 2.6. The lower the NNT the more effective the analgesic hence the complainant suggested that by not comparing Tramacet with co-codamol 60/1000 but only with 60/600, showed Tramacet in a more favourable light.

Co-codamol 30/500 was available for prescription with the recommendation that one to two tablets might be taken every four hours up to a maximum of eight tablets daily. Tramacet was indicated for the symptomatic treatment of moderate to severe pain, hence the appropriate comparator indications should also be for moderate to severe pain. Under these circumstances, it was most likely that two tablets of co-codamol would be prescribed rather than one, giving a total dose of 60mg codeine phosphate combined with 1000mg paracetamol ie 60/1000 as advised by the complainant.

The comparative dose, ie co-codamol 60/600, had been selected because direct comparative clinical trials of co-codamol at that dose and Tramacet had been published (Mullican and Lacy, 2001). Given, however, that co-codamol 60/1000 was available as a recommended prescription dose then this dose should have been included in the advertisement.

Janssen-Cilag therefore admitted breaches of Clauses 7.2 and 7.3 of the Code in that the comparison was not

based on an evaluation of all of the evidence nor did it reflect that evidence clearly. The comparison was therefore misleading as it did not include the co-codamol 60/1000 data.

After receiving the complaint an immediate review of the electronic advertisement was undertaken in respect of the complainant's comments and upon realising the error, the advertisement was immediately removed from the website that day and was no longer available for health professionals to view. Review of all promotional items currently in use for Tramacet indicated that the advertisement in question was the only promotional item which contained the comparative data which was the subject of this complaint.

Janssen-Cilag apologised for this oversight and gave an undertaking that in future advertisements, where using the NNT comparative criteria, that the comparison with co-codamol 60/1000 would be used with its NNT value of 2.2.

PANEL RULING

The Panel considered that by omitting the NNT data for co-codamol 60/1000 the comparison was misleading as alleged. The Panel ruled breaches of Clauses 7.2 and 7.3 of the Code as acknowledged by Janssen-Cilag.

During its consideration of this case the Panel noted that readers were invited to claim a free stethoscope. The Panel queried whether the offer met the requirements of the supplementary information to Clause 18.2 that promotional aids must cost the donor company no more than £6 excluding VAT and have a similar perceived value to the recipient. The Panel decided to take this matter up with the company as a complaint in accordance with Paragraph 17 of the Constitution and Procedure for the Authority (Case AUTH/1879/7/06).

Complaint received **18 July 2006**

Case completed **30 August 2006**