

ANONYMOUS v BAYER SCHERING PHARMA

Promotion of Nebido

An anonymous ex-employee complained that an advertisement for Nebido (long-acting testosterone injection) implied that the product would enable men to become sexually attractive to younger women which was not a licensed indication. The complainant noted in particular a photograph in the advertisement of a gentleman of advancing years, apparently hailing a taxi and accompanied by a woman who looked significantly younger than him clutching his arm.

The Panel did not consider that the advertisement promoted Nebido for an unlicensed indication as alleged. The advertisement reflected the positive effects of treating hypogonadism leading to, *inter alia*, restoration of libido. No breach of the Code was ruled.

An anonymous ex-employee of Bayer Schering Pharma complained about an advertisement for Nebido (long-acting testosterone injection) published in the BMJ 3 May 2008.

COMPLAINT

The complainant stated that the advertisement in question included a picture of a gentleman of advancing years who appeared to be hailing a taxi with a woman who looked significantly younger than him clutching his arm. This picture implied that taking Nebido would enable men to become sexually attractive to younger women. This was not a licensed indication for Nebido.

The complainant alleged the advertisement was in breach of Clauses 2, 3.2 and 9.1 of the Code.

RESPONSE

Bayer Schering submitted that the advertisement in question was a fair, accurate and balanced representation of the effects of the treatment of male hypogonadism using Nebido therapy and did not contravene any clause of the Code.

Nebido was indicated for male hypogonadism when testosterone deficiency had been confirmed by clinical features and biochemical tests. The accepted features of hypogonadism were described in a consensus statement of the International Society of Andrology, International Society of the Study of the Aging Male and the European Association of Urology as a syndrome characterised by decrease in cognitive functions, fatigue, diminished sexual desire (libido) and depressed mood. Furthermore the Klinefelter's Syndrome

Association recognised that patients with hypogonadism might experience body image issues and a lessened capacity for enjoyment which led to some untreated hypogonadal patients leading relatively sedentary and insular lives.

In the hypogonadal man, Nebido restored serum testosterone levels to the physiological range which led to the normalisation of hypogonadal symptoms such as improved feeling of wellbeing, improved emotional stability, restoration of libido and increases in muscle mass.

There were also data to demonstrate that Nebido achieved therapeutic effects without the peaks and troughs in serum testosterone levels associated with shorter-acting testosterone injections. More importantly Nebido achieved these effects following the administration of three to five injections per year which was fewer than short-acting preparations which required approximately seventeen injections per year, affording Nebido patients fewer visits to the clinic to receive their treatment, which was the subject of the advertisement in question.

The advertisement importantly depicted the symptomatic improvement to patients when their testosterone levels were restored and maintained within the normal physiological range. The patient was able to conduct typical, normal activities demonstrating restoration of positive mood, concentration, energy and sexual interest. The man and women featured in the advertisement were aged 57 and 45 years old respectively; the man's age was entirely appropriate for a patient with late-onset hypogonadism.

The advertisement in question was therefore balanced and accurate. It did not suggest that treated patients were more attractive to younger women.

Bayer Schering totally refuted the complainant's allegations that the advertisement was in breach of Clauses 2, 3.2 and 9.1 of the Code. The advertisement presented a fair, balanced and accurate view of the symptomatic improvements which hypogonadal patients experienced when their serum testosterone levels were restored to and maintained within the accepted physiological range. The claims were factually correct, consistent with the summary of product characteristics (SPC) and current international guidelines and were fully referenced to well-respected publications. The pictures were in good taste and depicted a man and woman who were of an appropriate age carrying out typical, normal activities.

PANEL RULING

The Panel noted that the advertisement included four photographs. The one commented on by the complainant was of a man apparently hailing a taxi. He was accompanied by a woman, clutching his arm, who was half turned away from the camera. Her face could not be seen. The other three photographs were of the same man alone in different situations.

The Panel noted that Nebido was authorized for testosterone replacement therapy for male hypogonadism when testosterone deficiency had been confirmed by clinical features and biochemical tests.

The Panel did not consider that the advertisement promoted an unlicensed indication as alleged. Nor had the advertisement failed to maintain a high standard. The four photographs reflected the positive effects of treating hypogonadism such as improvements in well-being and restoration of libido.

No breach of Clauses 3.2 and 9.1 was ruled. Given its ruling of no breach the Panel did not consider the circumstances warranted a ruling of a breach of Clause 2 of the Code which was used as a sign of particular censure.

Complaint received **6 May 2008**

Case completed **23 May 2008**
