CASE AUTH/2130/6/08

GENERAL PRACTITIONER v PFIZER

Toviaz journal advertisement

A general practitioner complained about an advertisement for Toviaz (fesoterodine fumarate) placed by Pfizer in GP, 6 June. Pfizer also marketed Detrusitol (tolterodine). Both products were for the symptomatic treatment of patients with overactive bladder syndrome (OAB).

The complainant noted that the advertisement for Toviaz also promoted tolterodine for the same indication. The complainant was concerned that the standards pertaining to ensuring prescriber confidence, and therefore patient safety, had been seriously compromised by the omission of the tolterodine prescribing information as required by the Code.

The absence of the tolterodine prescribing information in this advertisement was misleading and potentially harmful to patients because the prescriber could not assess the relationship of the prescribing information to the promotional claims and indications for tolterodine. Consequently prescribers were unlikely to be able to make an entirely rational/informed prescribing decision with respect to tolterodine.

Given the very serious and obvious breach of the Code, and the likelihood that it impacted other Toviaz promotional materials and activities, the Authority should require Pfizer to immediately withdraw all affected materials. This would ensure continued confidence amongst prescribers that the lengthy timelines often associated with the complaints procedure did not provide the opportunity for Pfizer to obfuscate from its responsibilities and continue disseminating incomplete, misleading and potentially harmful promotional materials.

The Panel considered that, although only referred to by its non-proprietary name, the advertisement nonetheless promoted Detrusitol; prescribing information should have been provided. Given that the prescribing information had not been provided the Panel ruled a breach of the Code as acknowledged by Pfizer.

The Panel did not consider that the lack of prescribing information for Detrusitol rendered the advertisement misleading. The Panel further did not consider that the absence of the prescribing information meant that the advertisement had not encouraged the rational use of Detrusitol. No breach of the Code was ruled.

A general practitioner complained about an advertisement (ref TOV097b) for Toviaz (fesoterodine fumarate) placed by Pfizer Limited in GP, 6 June. Pfizer also marketed Detrusitol (tolterodine). Both products were for the symptomatic treatment of patients with overactive bladder syndrome (OAB).

COMPLAINT

The complainant stated that in support of its promotion of Toviaz, Pfizer relied on the following statements: 'From Pfizer, the maker of tolterodine, Toviaz is a new step in the treatment of OverActive Bladder.' and 'Toviaz 8mg demonstrated improvements with statistical significance vs. tolterodine ER in important treatment outcomes. Tolterodine is the market leading therapy in OAB'.

It therefore appeared that alongside promoting Toviaz for the treatment of OAB, Pfizer had also promoted tolterodine for the same indication.

The complainant was concerned that the standards pertaining to ensuring prescriber confidence, and therefore patient safety, had been seriously compromised in this advertisement by the omission of the tolterodine prescribing information as was required by the Code.

The extent and gravity of this omission invited the question whether Pfizer really understood its responsibilities to prescribers and patients and why it was that the Authority described the provision of prescribing information as 'obligatory information'.

The absence of the tolterodine prescribing information in this advertisement was misleading and potentially harmful to patients because the prescriber could not assess the relationship of the information that one would normally have expected to be specified in the prescribing information to the promotional claims and indications being made for tolterodine. Consequently, based on the advertisement, prescribers were unlikely to be able to make an entirely rational/informed prescribing decision with respect to tolterodine.

Given the very serious and obvious breach of the Code, and the likelihood that it impacted other promotional materials and activities supporting Toviaz, the Authority should require that Pfizer urgently remedy this matter by withdrawing immediately all affected materials. This would ensure continued confidence amongst prescribers that the lengthy timelines often associated with the complaints procedure did not provide the opportunity and platform for Pfizer to obfuscate from its responsibilities and continue disseminating incomplete, misleading and potentially harmful

promotional materials.

When writing to Pfizer, the Authority asked it to respond in relation to Clauses 4.1, 7.2 and 7.10 of the Code.

RESPONSE

Pfizer accepted that the statement 'Tolterodine is the market leading therapy in OAB' could be considered as a promotional claim for tolterodine which therefore required prescribing information to be provided as part of the advertisement. Since this had not been provided Pfizer acknowledged a breach of Clause 4.1.

Pfizer stated that as it aimed to uphold the highest standards of professional practice and compliance with the Code it would immediately cease any further publication of this advertisement and ensure that all similar promotional material was reviewed to ensure all relevant prescribing information was provided. Pfizer noted that due to publication processes, it was not possible to immediately amend or withdraw the advertisement from two publications. Pfizer provided a list of journals containing the advertisement which had either been published or where it had been unable to immediately amend or withdraw the advertisement.

Pfizer denied a breach of Clause 7.2 of the Code. The claim 'Toviaz 8mg demonstrated improvements with statistical significance vs. tolterodine ER in important treatment outcomes' could be substantiated with Chapple *et al*, accepted for publication by the British Journal of Urology International. The claim 'Tolterodine is the market leading therapy in OAB' was substantiated by market research data.

Pfizer did not consider that Clause 7.10 had been breached as there was no element of exaggeration or lack of objectivity.

PANEL RULING

The Panel considered that, although only referred to by its non-proprietary name, the advertisement nonetheless promoted Detrusitol; prescribing information should have been provided. Given that the prescribing information had not been provided the Panel ruled a breach of Clause 4.1 as acknowledged by Pfizer.

The Panel did not consider that the lack of prescribing information for Detrusitol rendered the advertisement misleading. No breach of Clause 7.2 was ruled. The Panel further did not consider that the absence of the prescribing information meant that the advertisement had not encouraged the rational use of Detrusitol. No breach of Clause 7.10 was ruled.

Complaint received **9 June 2008**

Case completed **10 July 2008**