CASE AUTH/2167/9/08

ASTELLAS PHARMA v PFIZER

Promotion of Toviaz

Astellas Pharma complained about the promotion of Toviaz (fesoterodine) by Pfizer. Pfizer also supplied Detrusitol (tolterodine).

The detailed response from Pfizer is given below.

Astellas stated that despite agreeing on 17 June to include Detrusitol prescribing information in Toviaz materials which contained claims about tolterodine, Pfizer distributed materials without the Detrusitol prescribing information at a national urology meeting, 23-27 June. This issue had already been the subject of Case AUTH/2130/6/08 about a Toviaz journal advertisement which referred to tolterodine but did not include the relevant prescribing information.

This demonstrated an unnecessary delay in withdrawing materials known to be in breach of the Code. Pfizer had told Astellas that it decided to withdraw materials without the necessary prescribing information too late to remove offending articles from the stand. Given that they were simply materials available for delegates to pick up, it would clearly have been possible simply to remove the offending items, and Astellas believed therefore that this behaviour demonstrated a cynical disregard for the Code and risked bringing discredit to the industry in breach of Clause 2.

The Panel noted that the lack of prescribing information on the materials at the Pfizer stand was covered by its ruling of a breach of the Code in Case AUTH/2130/6/08. The urology meeting had been held on 23-27 June. Although Pfizer acknowledged a breach in its response of 25 June, the company was not obliged to withdraw material until it accepted the Panel's ruling of a breach (10 July) following notification on 27 June. As the urology meeting was held at a time when Pfizer had yet to give its undertaking, it was not in breach of that undertaking to continue to use the material at issue. Such action was not outwith the Constitution and Procedure and thus no breach of Clause 2 was ruled. However given that Pfizer had acknowledged a breach of the Code, the Panel considered that it would have been helpful if the materials at issue had been removed from the stand. The Panel considered that although Pfizer had acted within the letter of the Code it queried whether it had acted within the spirit.

Astellas alleged that the claim 'By the end of treatment, Toviaz 8mg was significantly better than tolterodine ER 4mg in improving a number of important endpoints; specifically, severe urgency with UUI [urgency urinary incontinence] per 24 hours, mean volume voided per micturition, continent days per week and UUI episodes per 24 hours*' in a journal advertisement was not a balanced, fair and objective representation of the evidence available and hence was misleading. Astellas had repeatedly brought this issue to Pfizer's attention but had failed to reach an agreement. Astellas was particularly concerned that the claim was derived from a post hoc analysis. Further, the parameters at issue appeared to be a cherry-picked selection of both co-primary and secondary parameters from the original study.

The Panel noted that the claim at issue had been the subject of Case AUTH/2150/7/08, considered by the Panel and the Appeal Board. In Case AUTH/2150/7/08, the Panel noted that the study to which the claim was referenced (Chapple *et al* 2008) was a post hoc analysis of a phase 3 study by Chapple *et al* (2007). The original study had investigated the efficacy, tolerability and safety of Toviaz 4mg and 8mg vs placebo in overactive bladder (OAB). The study included a tolterodine ER 4mg arm as an active control. Both doses of Toviaz were significantly better than placebo in improving the symptoms of OAB. Efficacy was more pronounced with Toviaz 8mg than with other treatments. The post hoc study extracted from the original study only the data relating to Toviaz 8mg, tolterodine ER 4mg and placebo and examined the results for the primary endpoint (voids/24h), the two co-primary endpoints (UUI episodes/24h and treatment response), several secondary endpoints and health related quality of life (HRQoL). The data showed that by week 12 patients in both active-treatment groups showed significant improvements in most bladder diary variables and treatment response rates compared with placebo. Toviaz 8mg was statistically significantly better than tolterodine ER 4mg for improving UUI episodes, severe urgency plus UUI, mean voided volume and number of continent days/week. In addition the Toviaz and tolterodine groups showed significantly greater improvements in HRQoL than the placebo group. A major improvement in the severity of bladder-related problems was reported by 39% of the Toviaz group and 34% of the tolterodine ER groups v 25% of those on placebo ($p \leq 0.01$). The author stated that one of the limitations of the study was that it was a post hoc analysis of a study which was not powered for a comparison between active treatments or for HRQoL. Prospective studies were under way. The lack of consensus on measurement of the urgency classification was described as another shortcoming.

With regard to the second advertisement (TOV162)

the Panel noted that it was a well established principle under the Code that a claim could not be qualified by a footnote. It considered that given the statements in Chapple *et al* (2008) about the limitations of the study, the fact that it was a post hoc analysis and that Chapple *et al* (2007) was not powered for a between treatments comparison meant that the claim 'Toviaz 8mg was significantly better than tolterodine ER 4mg in improving a number of important endpoints; specifically…' was misleading and not capable of substantiation. Breaches of the Code had been ruled.

The position was further confused by the second part of the footnote 'Starting dose 4mg titrated up to 8mg for more efficacy'. This did not apply to Chapple *et al* (2007) where patients received medicine at the same dose throughout the study. It appeared to be more general information about the use of Toviaz as according to its summary of product characteristics (SPC) the recommended starting dose of 4mg once daily could, according to individual response, be increased to 8mg once daily (the maximum daily dose).

Overall, the Panel considered that high standards had not been maintained and a breach of the Code had been ruled.

Upon appeal by Pfizer of the Panel's rulings of breaches of the Code, the Appeal Board considered that the claim at issue, '… Toviaz 8mg was significantly better than tolterodine ER 4mg in improving a number of important endpoints; …' also referenced to Chapple *et al* (2008) implied statistical significance which was not so. The Appeal Board did not accept Pfizer's submission at the appeal that it was not claiming statistically significant superiority. There was a clear claim of superiority in the advertisement and this would be read as being clinically and statistically significant. The statistical analysis plan for Chapple (2008) had stated that the comparison of the two doses of Toviaz with tolterodine ER would only be done as an exploratory analysis and no p-values would be provided. Although a footnote stated 'Analysis of Toviaz 8mg v tolterodine ER was not part of the original study plan' otherwise misleading claims could not be so qualified. The Appeal Board considered that given the data upon which it was based, the claim was misleading and had not been substantiated. The Appeal Board upheld the Panel's rulings of breaches of the Code.

The position was further confused by a second footnote which stated 'Starting dose 4mg titrated up to 8mg for more efficacy'. This did not apply to Chapple *et al* where patients received Toviaz at the same dose (4mg or 8mg) throughout. It appeared that the footnote gave more general information about the use of Toviaz; according to its SPC the recommended starting dose was 4mg once daily which could, according to individual response, be increased to 8mg once daily (the maximum daily dose).

Overall, the Appeal Board considered that high standards had not been maintained and it upheld the Panel's ruling of a breach of the Code.

In the current case, Case AUTH/2167/9/08, the Panel considered that the previous rulings of breaches of the Code in Case AUTH/2150/7/08 applied here. The Panel considered that the comparison was misleading and a breach was ruled. The rational use of Toviaz was not encouraged and a breach was ruled.

In relation to the claim 'Toviaz is a new step in the treatment of Overactive Bladder', Astellas stated that Toviaz was an anti-muscarinic as were a number of currently available OAB treatments. Indeed the active metabolite of Toviaz was the same as that of tolterodine which had been available for many years, and the main difference between Toviaz and tolterodine was the route of metabolism. The term 'new step' inferred that Toviaz was either a completely new type of medicine for OAB, perhaps belonging to a new class or providing a new mechanism of action or administration, or provided an alternative way of treating the condition, rather than being an alternative anti-muscarinic adding to the choice of those available. Astellas did not consider that Toviaz offered a novel step or a breakthrough in the management of OAB. Astellas alleged that the claim was misleading as it implied that Toviaz had some special merit over other currently available treatments which it clearly had not.

The Panel considered that the phrase 'a new step' might be read as implying that Toviaz was a completely new approach for treating OAB. The claim appeared as a heading to two bullet points, the second of which was the claim comparing Toviaz and tolterodine ruled in breach above. According to Pfizer, Toviaz was metabolised to its active form by a different pathway compared with tolterodine (which had the same active metabolite). Toviaz was available in two doses unlike tolterodine. Pfizer submitted that Toviaz was a new step for Pfizer in the treatment of OAB. There was no claim for a novel step or breakthrough in management of OAB as alleged. The advertisement included a black triangle to denote that special reporting was required in relation to adverse events. Nonetheless, the Panel considered that the claim '… a new step…' implied more than just a new anti-muscarinic and in that regard it was misleading and could not be substantiated. Thus the Panel ruled breaches of the Code.

Astellas Pharma Ltd complained about the promotion of Toviaz (fesoterodine) by Pfizer Limited. Pfizer also supplied Detrusitol (tolterodine). Astellas supplied Vesicare (solifenacin). Astellas stated that inter-company dialogue had left three issues unresolved. Pfizer stated that it had worked closely and in a timely fashion to address the concerns of Astellas. However, additional information had been included in the complaint which it had not had the chance to discuss with

Astellas. No further details were provided in this regard.

This case was considered under the 2008 Constitution and Procedure. The clauses cited by Astellas, Clauses 2, 4.1, 7.2, 7.3, 7.4 and 7.10 were the same in the 2008 Code as in the 2006 Code.

1 Undertaking and withdrawal of material by Pfizer

COMPLAINT

Astellas stated that following agreement on 17 June that Detrusitol prescribing information should be included with materials which contained claims relating to tolterodine, Pfizer continued to distribute such materials on its stand at the British Association of Urological Surgeons (BAUS) Annual Meeting, Manchester, 23-27 June. This issue had already been the subject of a complaint (Case AUTH/2130/6/08) about a Toviaz journal advertisement which referred to tolterodine but did not include the relevant prescribing information. However, Pfizer continued to use materials on its stand at the BAUS conference with claims about tolterodine which did not contain the necessary prescribing information (ref TOV093) in breach of Clause 4.1.

This demonstrated an unnecessary delay in withdrawing materials known to be in breach of the Code. Pfizer had told Astellas that it decided to withdraw materials without the necessary prescribing information too late to remove offending articles from the stand. Given that they were simply materials available for delegates to pick up, it would clearly have been possible simply to remove the offending items, and Astellas believed therefore that this behaviour demonstrated a cynical disregard for the Code and risked bringing discredit to the industry in breach of Clause 2.

RESPONSE

Pfizer stated that it received a complaint from an anonymous GP on 10 June (Case AUTH/2130/6/08) regarding the omission of tolterodine prescribing information on a Toviaz advertisement (TOV097b), just prior to the complaint it received from Astellas on 13 June. Pfizer responded to the Authority on 25 June and accepted a breach of Clause 4.1 regarding another advertisement (TOV162). On 10 July Pfizer returned its undertaking that all materials would be corrected to ensure they were compliant. Pfizer had complied fully with this undertaking, and all materials which referred to tolterodine were subsequently updated to include the appropriate prescribing information.

PANEL RULING

The Panel noted that the lack of prescribing information on the materials at the Pfizer stand was covered by its ruling of a breach of Clause 4.1 in Case AUTH/2130/6/08. The Panel noted that the BAUS meeting had been held on 23-27 June. Although Pfizer acknowledged a breach of Clause 4.1 in its response of 25 June, the company was not obliged to withdraw material until it accepted the Panel's ruling of a breach of the Code (10 July 2008) following notification on 27 June. As the BAUS meeting was held at a time when Pfizer had yet to give its undertaking, it was not in breach of that undertaking to continue to use the material at issue. Such action was not outwith the Constitution and Procedure and thus no breach of Clause 2 was ruled. However given that Pfizer had acknowledged a breach of Clause 4.1, the Panel considered that it would have been helpful if the materials at issue had been removed from the stand. The Panel considered that although Pfizer had acted within the letter of the Code it queried whether it had acted within the spirit.

2 Journal Advertisement (ref TOV162)

a Claim 'By the end of treatment, Toviaz 8mg was significantly better than tolterodine ER 4mg in improving a number of important endpoints; specifically, severe urgency with UUI [urgency urinary incontinence] per 24 hours, mean volume voided per micturition, continent days per week and UUI episodes per 24 hours*'

*** Analysis of Toviaz 8mg vs tolterodine ER was not part of the original study plan**

This claim was referenced to Chapple *et al*, article in press (Chapple *et al* 2008).

COMPLAINT

Astellas believed that this claim was not a balanced, fair and objective representation of the evidence available and hence was misleading. Astellas had repeatedly brought this issue to Pfizer's attention but had failed to reach an agreement. Astellas had asked an eminent statistician for an independent expert opinion on this claim in light of the current publicly available data. His report was provided.

Astellas alleged that the claim was in breach of Clauses 7.2, 7.3, 7.4 and 7.10.

- A post hoc analysis could not be used as the sole source of a claim, even if it was corrected for multiplicity. Findings from a post hoc analysis were exploratory and could not be considered as confirmatory in the absence of other relevant data. This claim appeared to be in breach of Clause 7.2.
- This claim originated from a post hoc analysis in which there was no multiplicity correction. In the referenced paper there was clear avoidance of specifying a sequential testing strategy in line with that used in the original study (Chapple *et al* 2007). If such a strategy was followed then no difference between Toviaz 8mg and tolterodine

4mg would have been observed (on change from baseline in micturition frequency) and thus no further tests would have been conducted. Therefore, the conclusion must be that this claim was not supported by a sound statistical basis and was in breach of Clause 7.2 (supplementary information).

- The parameters included in this claim, namely 'severe urgency with UUI per 24 hours, mean volume voided per micturition, continent days per week and UUI episodes per 24 hours', were only those which achieved an unadjusted p value of <0.05, and appeared to be a cherry-picked selection of both co-primary and secondary parameters from the original study. Astellas noted that there were four symptoms of overactive bladder (OAB): urgency, UUI, micturition frequency and nocturia. Only one of these symptoms was included in this claim. Regarding urgency, the claim referred only to those suffering from severe urgency, perhaps because there was no difference in overall urgency. Therefore the part of the claim referring to 'important endpoints' was misleading as three of the four key OAB symptoms were not included. This appeared, therefore, to be a breach of Clauses 7.3 and 7.4. The claim did not reflect all available evidence in breach of Clause 7.2. Furthermore, the failure to present all the evidence available such that the prescriber could make a rational decision about the use of Toviaz was in breach of Clause 7.10.

RESPONSE

Pfizer stated that it had updated its materials specifically relating to the claim at issue to make it clear which treatment endpoints had reached statistical significance.

Pfizer accepted a breach of Clause 7.2 for the previous advertisement TOV097b (Case AUTH/2150/7/08) as it agreed with the Authority that the claim 'Toviaz 8mg demonstrated improvements with statistical significance vs tolterodine ER 4mg in important treatment outcomes' could be viewed as too general.

Substantiation by post hoc analysis

Pfizer submitted that provided the materials clearly contained context information on the nature of the data, so as to ensure the reader was not misled, post hoc analysis could be used. This matter was currently under review by the Code of Practice Appeal Board (Case AUTH/2150/7/08).

The claim at issue stated that the significant improvements with Toviaz 8mg compared with tolterodine ER 4mg were relevant to a number of defined endpoints. These endpoints were then clearly specified, with no indication that this statistical significance related to all endpoints measured. Furthermore, a footnote was added to provide further context on the analysis. The footnote ensured that the material was sufficiently complete to enable the reader to form their own opinion and did not qualify the claim.

Pfizer therefore did not agree that the claim was not substantiated by the referenced data or was misleading and was therefore not in breach of Clauses 7.2 or 7.4.

Statistical analysis

Although the statistical methods used in post hoc analysis might be similar to the primary methods used in a study, they did not necessarily follow the same approach regarding control for error rates. The closed-testing methodology used in the analysis of the three co-primary endpoints in the original Toviaz phase 3 trials was appropriate for controlling experiment-wise error rates. When performing post hoc analyses it was typical to report p values without adjustments, in order to help understand treatment differences separately, and not in the context of the overall error rate that also considered other comparisons. Generating individual comparison p values was an accepted and common practice in post hoc and secondary analyses.

Whilst the comparison of the two Toviaz doses to tolterodine ER was not the primary endpoint in the phase 3 trials, it was of clinical interest and had been pre-specified in the statistical analysis plan. The comparison was carried out on the full analysis set with the last observation carried forward, and the patient populations were not selected, altered or modified compared to that used for the pre-specified analyses.

The results for the co-primary endpoint urge incontinence showed that the 95% confidence interval for the treatment difference of 0.48 episodes/day between Toviaz 8mg and tolterodine ER 4mg was (-0.92; -0.05). Since this did not contain zero this indicated a difference between the two treatments with respect to urge incontinence.

The statistical methods used for the comparison of Toviaz 8mg with tolterodine ER were clearly described in the manuscript, which was accepted for publication following peer review and considered level 1b evidence by The British Journal of Urology International, a well respected, peer-reviewed journal.

Pfizer therefore did not agree that the claim was not substantiated by the referenced data, and therefore was not in breach of Clause 7.2.

Parameters included within claim

Toviaz and tolterodine were licensed for the treatment of symptoms of OAB syndrome which was defined as urgency, with or without urinary incontinence, often with frequency or nocturia. The parameters included in this claim – urgency,

incontinence and mean voided volume – were reported verbatim from the authors' published conclusions that these were important in the treatment of this condition and were three of five bladder variables that had been shown to be central to OAB.

Pfizer therefore did not agree that the claim at issue was in breach of Clauses 7.2, 7.3, 7.4 or 7.10.

PANEL RULING

The Panel noted that the claim at issue had been the subject of Case AUTH/2150/7/08, considered by the Panel and the Appeal Board as follows:

Case AUTH/2150/7/08

The Panel noted that the study to which the claim was referenced (Chapple *et al* 2008) was a post hoc analysis of a phase 3 study by Chapple *et al* (2007). The original study had investigated the efficacy, tolerability and safety of Toviaz 4mg and 8mg vs placebo in OAB. The study included a tolterodine ER 4mg arm as an active control. Both doses of Toviaz were significantly better than placebo in improving the symptoms of OAB. Efficacy was more pronounced with Toviaz 8mg than with other treatments. The post hoc study extracted from the original study only the data relating to Toviaz 8mg, tolterodine ER 4mg and placebo and examined the results for the primary endpoint (voids/24h), the two co-primary endpoints (urgency urinary incontinence (UUI) episodes/24h and treatment response), several secondary endpoints and health related quality of life (HRQoL). The data showed that by week 12 patients in both active-treatment groups showed significant improvements in most bladder diary variables and treatment response rates compared with placebo. Toviaz 8mg was statistically significantly better than tolterodine ER 4mg for improving UUI episodes, severe urgency plus UUI, mean voided volume and number of continent days/week. In addition the Toviaz and tolterodine groups showed significantly greater improvements in HRQoL than the placebo group. A major improvement in the severity of bladder-related problems was reported by 39% of the Toviaz group and 34% of the tolterodine ER groups v 25% of those on placebo ($p \leq 0.01$). The author stated that one of the limitations of the study was that it was a post hoc analysis of a study which was not powered for a comparison between active treatments or for HRQoL. Prospective studies were under way. The lack of consensus on measurement of the urgency classification was described as another shortcoming.

With regard to the second advertisement (TOV162) the Panel noted that it was a well established principle under the Code that a claim could not be qualified by a footnote. It considered that given the statements in Chapple *et al* (2008) about the limitations of the study, the fact that it was a post hoc analysis and that Chapple *et al* (2007) was not powered for a between treatments comparison meant that the claim 'Toviaz 8mg was significantly better than tolterodine ER 4mg in improving a number of important endpoints; specifically…' was misleading and not capable of substantiation. Breaches of Clauses 7.2 and 7.4 were ruled

The position was further confused by the second part of the footnote 'Starting dose 4mg titrated up to 8mg for more efficacy'. This did not apply to Chapple *et al* (2007) where patients received medicine at the same dose throughout the study. It appeared to be more general information about the use of Toviaz as according to its summary of product characteristics (SPC) the recommended starting dose of 4mg once daily could, according to individual response, be increased to 8mg once daily (the maximum daily dose).

Overall, the Panel considered that high standards had not been maintained and a breach of Clause 9.1 was ruled.

The Panel noted that Clause 2 was reserved as a sign of particular censure. It considered on balance that the circumstances did not warrant a ruling of a breach of that clause. This ruling was upheld by the Appeal Board upon appeal by the complainant.

Upon appeal by Pfizer of the Panel's rulings of breaches of the Code, the Appeal Board considered that the claim at issue, '… Toviaz 8mg was significantly better than tolterodine ER 4mg in improving a number of important endpoints; …' also referenced to Chapple *et al* (2008) implied statistical significance which was not so. The Appeal Board did not accept Pfizer's submission at the appeal that it was not claiming statistically significant superiority. There was a clear claim of superiority in the advertisement and this would be read as being clinically and statistically significant. The statistical analysis plan for Chapple (2008) had stated that the comparison of the two doses of Toviaz with tolterodine ER would only be done as an exploratory analysis and no p-values would be provided. Although a footnote stated 'Analysis of Toviaz 8mg v tolterodine ER was not part of the original study plan' otherwise misleading claims could not be so qualified. The Appeal Board considered that given the data upon which it was based, the claim was misleading and had not been substantiated. The Appeal Board upheld the Panel's rulings of breaches of Clauses 7.2 and 7.4. The appeal on this point was unsuccessful.

The position was further confused by a second footnote which stated 'Starting dose 4mg titrated up to 8mg for more efficacy'. This did not apply to Chapple *et al* where patients received Toviaz at the same dose (4mg or 8mg) throughout. It appeared that the footnote gave more general information about the use of Toviaz; according to its SPC the recommended starting dose was 4mg once daily which could, according to individual response, be increased to 8mg once daily (the maximum daily dose).

Overall, the Appeal Board considered that high standards had not been maintained and it upheld the Panel's ruling of a breach of Clause 9.1. The appeal on this point was unsuccessful.

During its consideration the Appeal Board noted that the Toviaz SPC stated that 'The recommended starting dose is 4mg once daily. Based upon individual response, the dose may be increased to 8mg once daily. The maximum daily dose is 8mg'. The Appeal Board noted that in Chapple *et al* (2007) patients were started on either a 4mg or 8mg dose of Toviaz. The patients started on the maximum daily dose of 8mg Toviaz had not been treated in accordance with the Toviaz SPC.

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The Panel considered that the previous rulings of breaches of Clauses 7.2 and 7.4 in Case AUTH/2150/7/08 applied here. With regard to the alleged breach of Clause 7.3 the Panel considered that the comparison was misleading and a breach was ruled. The rational use of Toviaz was not encouraged and a breach of Clause 7.10 was also ruled.

b Claim 'Toviaz is a new step in the treatment of Overactive Bladder'

COMPLAINT

Astellas stated that throughout much of its launch campaign Toviaz was claimed to be a 'new step' in the treatment of OAB. However, Toviaz was an anti-muscarinic as were a number of currently available OAB treatments. Indeed the active metabolite of Toviaz was the same as that of tolterodine which had been available for many years, and the main difference between Toviaz and tolterodine was the route of metabolism.

The term 'new step' inferred that Toviaz was either a completely new type of medicine for use in this disease area, perhaps belonging to a new class or providing a new mechanism of action or administration, or provided an alternative way of treating the condition, rather than being an alternative anti-muscarinic adding to the choice of those available. Astellas did not consider that Toviaz offered a novel step or a breakthrough in the management of OAB.

Astellas alleged that the claim was misleading in breach of Clauses 7.2, 7.3, 7.4 and 7.10 as it implied that Toviaz had some special merit over other currently available pharmaceutical agents for the treatment of OAB which it clearly had not.

RESPONSE

Pfizer believed that Toviaz might be described as a 'new step in the treatment of overactive bladder' because:

- it was a new anti-muscarinic, launched by Pfizer which currently manufactured the UK's leading OAB product, Detrusitol (tolterodine)
- it contained fesoterodine which was activated by ubiquitous esterases to its active metabolite the 5-hydroxymethyl (5-HMT) derivative. This was distinctly different from tolterodine which was metabolised to 5-HMT via hepatic metabolism.
- it was licensed in two doses 4mg and 8mg – this was a new step to those who were familiar with the single dose limitation of tolterodine.
- it was an anti-muscarinic as were a number of other compounds currently available for OAB. Despite the availability of these products, clinicians and patients still needed additional therapeutic options.

Pfizer therefore did not agree that the claim was misleading or suggested any special merit or quality (Clauses 7.2, 7.10) as Pfizer clearly stated it was a new anti-muscarinic. The materials relating to this claim did not make any comparative claims (Clause 7.3). The statement could be substantiated by its activation process and available doses and therefore was not in breach of Clause 7.10.

PANEL RULING

The Panel considered that the phrase 'a new step' might be read as implying that Toviaz was a completely new approach for treating OAB. The claim appeared as a heading to two bullet points, the second of which was the claim comparing Toviaz and tolterodine ruled in breach in point 2a above. According to Pfizer, Toviaz was metabolised to its active form by a different pathway compared with tolterodine (which had the same active metabolite, 5-HMT). Toviaz was available in two doses unlike tolterodine. Pfizer submitted that Toviaz was a new step for Pfizer in the treatment of OAB. There was no claim for a novel step or breakthrough in management of OAB as alleged. The advertisement included a black triangle to denote that special reporting was required in relation to adverse events. Nonetheless, the Panel considered that the claim '… a new step…' implied more than just a new anti-muscarinic and in that regard it was misleading and could not be substantiated. Thus the Panel ruled breaches of Clauses 7.2, 7.3, 7.4 and 7.10.

Complaint received **16 September 2008**

Cases completed **14 November 2008**