CASE AUTH/2249/7/09

CONSULTANT UROLOGICAL SURGEON v GLAXOSMITHKLINE

Conduct of representatives

A consultant urological surgeon complained about the conduct of representatives from GlaxoSmithKline promoting Avodart (dutasteride). Previously, before the complainant had researched this himself, he accepted GlaxoSmithKline's claim that there were no comparative studies against the competitor finasteride. This happened again recently. However, there were comparative studies (which showed no advantage for the GlaxoSmithKline product) and indeed could be found through the GlaxoSmithKline website.

The complainant submitted that as this had happened in the past, and he suspected carried on, he believed it was a deliberate marketing strategy.

The detailed response from GlaxoSmithKline is given below.

The Panel noted that in the brief discussion between the complainant and the representative the representative, when asked if there had been any comparative studies between Avodart and finasteride, had stated 'No'. This was not so. In that regard the representative's response was wrong. The representative had not complied with all relevant requirements of the Code and had not maintained a high standard of ethical conduct. Breaches of the Code were ruled as acknowledged by GlaxoSmithKline.

The Panel was concerned that the complainant alleged that representatives had, on other occasions, stated that there were no comparative studies between Avodart and finesteride. No details were given in this regard by the complainant and the previous representative had left the company. The complainant had to establish his case on the balance of probabilities.

The Panel noted that the current Avodart training material referred to finasteride and in particular featured a graph comparing the suppression of dihydrotestosterone by Avodart and finasteride; the Avodart promotional material featured a similar graph. The Panel did not consider that the material encouraged representatives to deny that comparisons between Avodart and finasteride existed. In that regard the briefing material did not advocate a course of action which would be likely to lead to a breach of the Code and no breach was ruled.

A consultant urological surgeon from a general hospital complained about the conduct of representatives from GlaxoSmithKline UK Limited; he named one representative.

COMPLAINT

The complainant explained that he had been visited on a number of occasions by GlaxoSmithKline representatives trying to promote Avodart (dutasteride). Previously, before the complainant had researched this himself, he accepted GlaxoSmithKline's claim that there were no comparative studies against the competitor finasteride. This happened again recently with the representative in question. However, there were comparative studies (which showed no advantage for GlaxoSmithKline product) and indeed could be found through the GlaxoSmithKline website.

The complainant submitted that if it was just one individual one could assume that it was one rogue individual, but as it had happened in the past, and he suspected carried on, he now believed that this was a deliberate marketing strategy and amounted to lying. The complainant thought this was supposed to have been stopped after previous GlaxoSmithKline problems with anti-depressants.

When writing to GlaxoSmithKline the Authority asked it to respond in relation to the requirements of Clauses 7.2, 7.3, 15.2 and 15.9 of the Code.

RESPONSE

GlaxoSmithKline submitted that having investigated the complaint it accepted, and sincerely regretted, that the complainant was indeed misled by one of its representatives. The company accepted breaches of Clauses 7.2 and 15.2 of the Code.

However, GlaxoSmithKline firmly believed that the breaches which occurred were due to an error made by an individual representative and did not reflect any aspect of GlaxoSmithKline's marketing strategy. Specifically, GlaxoSmithKline did not accept that any of the comparisons between Avodart and finasteride made in its promotional materials contravened either Clause 7.2 or 7.3. GlaxoSmithKline also submitted that its representatives were provided with sufficient training (both in terms of seminar style teaching sessions and written briefing materials) to enable them to effectively promote Avodart without breaching the Code (Clause 15.9). Therefore Clauses 7.3 and 15.9 had not been breached.

Interaction between the representative and the complainant

GlaxoSmithKline submitted that the

representative's written account of his interaction with the complainant was as follows:

'I had an appointment to see the complainant after clinic.

The conversation followed as below –
***R** (representative), C (complainant).*

***R** - I am [name] the new urology representative from GSK. Can I start by asking if you have ever prescribed Avodart and in which patients?*

***C** - I have never prescribed Avodart and only use finasteride as there is no benefit of Avodart over finasteride and it is also cheaper.*

***R** - That is interesting. Please can I take a few minutes to show you some data to demonstrate the benefits of Avodart?*

***C** - Have there been any comparative studies between finasteride and Avodart?*

***R** - No, there have not....(C interrupted)*

***C** - There have been and I have seen them on your own SmithKline website and they showed no difference between the two. You have lied so please leave.*

***R** - Thank you for your time.*

I stood up and left the room.'

GlaxoSmithKline acknowledged that the representative's response to the complainant's question was incorrect; as the complainant noted, there had been a number of head-to-head studies comparing Avodart with finasteride.

When interviewed by his line manager, the representative clearly knew that there were a number of studies directly comparing Avodart and finasteride and accepted that his answer was incorrect. The representative stated that he felt flustered by being asked such a direct question right at the start of his meeting and that he gave an immediate incorrect answer under pressure rather than taking a moment to compose a more considered response. Before the representative had time to qualify his response he was asked to leave. Sales material which the representative had with him at the time and intended to talk through with the complainant included comparisons between Avodart and finasteride.

Abstracts pertaining to GlaxoSmithKline's sponsored studies were publicly available via gsk.com. There were nine abstracts on the website relating to head-to-head studies of Avodart and finasteride.

A number of studies which compared Avodart with finasteride were used in GlaxoSmithKline's promotional and training materials.

GlaxoSmithKline expected Avodart representatives to be fully conversant with these studies.

Promotional material available to Avodart representatives

GlaxoSmithKline provided all the relevant promotional materials available to Avodart representatives where a comparison between Avodart and finasteride was made. Within this material Avodart was compared to finasteride in three specific contexts:

Isoenzyme inhibition: GlaxoSmithKline claimed that finasteride was a selective inhibitor of the type 2 5α-reductase (5AR) isoenzyme whilst Avodart inhibited type 1 and type 2 5AR isoenzymes (Bartsch *et al* 2000 and Andriole *et al* 2004).

Dihydrotestosterone (DHT) suppression: A direct comparison between Avodart and finasteride was made relating to their effect in terms of suppressing levels of the androgen DHT. This claim was supported by a randomised controlled trial which compared the effects of Avodart and finasteride at their licensed doses in terms of DHT suppression (Clark *et al* 2007).

Retrospective efficacy study: The benign prostatic hyperplasia (BPH) cost model (provided) used a retrospective study which compared the clinical efficacy of Avodart and finasteride (Issa *et al* 2007). The nature of this study was clearly explained within the cost model.

Training and briefing materials provided to Avodart representatives

Before representatives were permitted to promote any product they must have:
- completed an initial generic two week in-house training programme covering topics such as the GlaxoSmithKline sales model, medical information resource and safety reporting, ethical requirements and the Code and NHS structures;
- completed a two week Avodart specific initial training programme (ITP) and
- passed an in-house examination to assess familiarity with the Code and passed an in-house examination to confirm satisfactory completion of the ITP.

As required by Clause 16.3, all representatives had to take and pass the ABPI Medical Representatives Examination within the prescribed time limit.

The representative in question joined GlaxoSmithKline in 2005 and promoted various GlaxoSmithKline products. Following successful completion of the Avodart ITP he started to promote Avodart in June 2009.

GlaxoSmithKline confirmed that the representative had:
- passed the ABPI representatives examination;
- completed an initial GlaxoSmithKline generic

training program in 2005;
- passed the internal ITP examination in June 2009 and
- completed the Avodart specific ITP course in June 2009.

GlaxoSmithKline advised that the Avodart ITP comprised the training manual, a 2 week ITP course and the ITP examination. The detailed training manual was circulated as pre-reading prior to the ITP course. The manual covered the male urogenital system, BPH and its diagnosis, treatment of BPH and the profile for dutasteride. The contents page relating to each module and those pages from within the manual which covered studies comparing Avodart to finasteride were provided.

The two week ITP course itself included sessions on a variety of clinical and non-clinical topics. Clinical sessions were delivered by members of the GlaxoSmithKline medical department with experience in the field of urology. Non-clinical sessions were mainly led by members of the Avodart marketing team. Training sessions were delivered in an interactive seminar style and used pre-approved PowerPoint presentations. Within the clinical sessions, studies comparing Avodart and finasteride were covered a number of times. The training slides which referred to such studies were provided. Non-clinical topics included an introduction to the Avodart marketing strategy, which was covered in some detail, and familiarisation with the available promotional material. Representatives were taken through presentations explaining how an interview with a health professional should be structured around the relevant detail aid. These presentations were provided. At no point during their training were representatives encouraged, explicitly or implicitly, to withhold information from health professionals with regard to those trials which directly compared Avodart with finasteride.

The written ITP multiple choice examination tested the candidate's understanding of the clinical data and marketing strategy which was covered on the course.

Action to mitigate the risk of similar breaches occurring in the future

GlaxoSmithKline submitted that on 24 July 2009 the representative in question was required to spend half a day with his line manager. During this session it was made clear that his actions had resulted in a breach of the Code. The representative clearly understood the seriousness of this issue and the fact that breaches of the Code might result in disciplinary action. The discussion moved on to cover the reasons why this breach occurred and consider how the representative could avoid making a similar error in the future. The representative was also required to spend half a day with a member of the GSK medical department; the agenda included:
- a review of all instances where trials comparing Avodart with finasteride were covered within the approved training materials;
- a review of currently available promotional materials focussing on those items where Avodart and finasteride were compared and
- an opportunity to practice, in a role-play setting, handling various questions health practitioners might raise regarding comparisons between Avodart and finasteride.

GlaxoSmithKline also considered it important to remind all other Avodart representatives of the key studies comparing Avodart with finasteride. At the next scheduled training event in September 2009, a member of the GlaxoSmithKline medical department would prepare an interactive teaching session covering all the key studies which had compared these two products.

Conclusion

GlaxoSmithKline accepted that the unfortunate actions of a single representative had resulted in breaches of Clauses 7.2 and 15.2. However, it was confident that the accuracy of its promotional material and the adequacy of the training given to its representatives before they were permitted to promote Avodart meant neither Clause 7.3 nor Clause 15.9 had been breached.

The complainant referred to previous interactions with Avodart representatives. The region in which the complainant worked was without an Avodart representative between July 2008 and July 2009. The previous representative no longer worked for GlaxoSmithKline so the company had not been able to investigate the element of the complaint which related to past activity. However, results from the key trials comparing Avodart with finasteride had been available for a number of years and GlaxoSmithKline was confident that Avodart representatives had been adequately briefed since the product was first promoted in the UK in 2003.

GlaxoSmithKline remained committed to the ethical promotion of its medicines and aimed, at all times, to comply with both the letter and the spirit of the Code.

PANEL RULING

The Panel noted that in the brief discussion between the complainant and the representative the representative, when asked if there had been any comparative studies between Avodart and finasteride, had stated 'No'. This was not so. In that regard the representative's response was wrong and so the Panel ruled a breach of Clause 7.2. The representative had not complied with all relevant requirements of the Code and had not maintained a high standard of ethical conduct. A breach of Clause 15.2 was ruled. GlaxoSmithKline had acknowledged these breaches of the Code.

The Panel was concerned that the complainant alleged that representatives had, on other

occasions, stated that there were no comparative studies between Avodart and finesteride. No details were given in this regard by the complainant and the previous representative had left the company. The complainant had to establish his case on the balance of probabilities.

The Panel noted that the current Avodart training material referred to finasteride and in particular featured a graph comparing the suppression of dihydrotestosterone by Avodart and finasteride; the Avodart promotional material featured a similar graph. The Panel did not consider that the material encouraged representatives to deny that comparisons between Avodart and finasteride existed. In that regard the briefing material did not advocate a course of action which would be likely to lead to a breach of the Code. No breach of Clause 15.9 was ruled.

Complaint received **15 July 2009**

Case completed **8 September 2009**