CASE AUTH/1922/11/06

VOLUNTARY ADMISSION BY GLAXOSMITHKLINE

Use of out of date prescribing information

GlaxoSmithKline voluntarily informed the Authority that out of date prescribing information had been used in Avandamet (rosiglitazone/metformin) advertisements from August 2006 until November 2006. As the Director considered that this was a potentially serious matter it was taken up and dealt with as a complaint under the Code in accordance with the Constitution and Procedure.

The Panel noted that for approximately three months Avandamet prescribing information had not referred to macular oedema as a serious but rare side effect. Given the theoretical implications for patient safety the Panel ruled breaches of the Code. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use.

GlaxoSmithKline UK Ltd voluntarily informed the Authority that out of date prescribing information had been used in Avandamet (rosiglitazone/metformin) advertisements from August 2006 until November 2006.

The action to be taken by the Authority in relation to a voluntary admission was set out in Paragraph 5.4 of its Constitution and Procedure which stated that the Director should treat the matter as a complaint if it related to a potentially serious breach of the Code or if the company failed to take action to address the matter. The Director considered that using incorrect prescribing information for a long period was a potentially serious matter and that the admission must accordingly be treated as a complaint.

COMPLAINT

GlaxoSmithKline stated that it considered itself to have been in breach of Clause 4 of the Code with respect to providing the most up-to-date prescribing information for advertisements for Avandamet.

The prescribing information was updated in August 2006, but the prescribing information dated April 2006 was used. This error was brought to GlaxoSmithKline's attention by Takeda in November. GlaxoSmithKline's normal procedure would be for the new prescribing information to be sent to the advertising agency and for the advertisement to be certified with a new code. GlaxoSmithKline stated that this was a one-off error, which occurred around a time of high staff turnover. GlaxoSmithKline immediately updated its procedures, to ensure that a change in staff would not cause the same error to recur. It had liaised with its advertising agency to ensure immediate insertion of the current prescribing information into all future advertisements.

Given the nature of the change to the prescribing information, GlaxoSmithKline did not consider that patients would have been put at serious risk.

GlaxoSmithKline invited the Authority to review the prescribing information for Avandia and Avandamet against the respective summaries of product characteristics (SPCs).

GlaxoSmithKline very much regretted the breach and reassured the Authority that it had taken appropriate steps to avoid any repeat of this error.

When writing to GlaxoSmithKline, the Authority asked it to respond in relation to Clauses 2, 4.1 and 9.1 of the Code.

RESPONSE

GlaxoSmithKline acknowledged that the out of date prescribing information had been used in 84 advertisements from 30 August 2006 until the end of November 2006; a list of the relevant publications was provided. GlaxoSmithKline therefore conceded a breach of Clause 4.1 as per its voluntary admission.

GlaxoSmithKline's standard procedure was that if there was a change to the SPC, the prescribing information was updated and certified, and a unique identifying number was raised for each size of advertisement requiring the updated prescribing information. A job bag was created, containing the new advertisement with the updated prescribing information, which was then reviewed by the medical

adviser, scientific adviser and marketing manager. The item was then certified by the medical adviser and the marketing manager and archived. GlaxoSmithKline provided the standard operating procedure 'Approval process for promotional items'. The updated advertisements were then sent to the advertising agency for placement.

In this instance, updated prescribing information was certified on 31 August 2006 following an update to the SPC in August. The main change to the prescribing information was the inclusion of macular oedema as a rare side effect. GlaxoSmithKline had already sent a 'Dear Doctor' letter (dated 20 December 2005) to alert prescribers to the case reports of macular oedema and inform them that the regulatory authorities were reviewing this new safety concern. Given that GlaxoSmithKline had proactively communicated the safety concern to all prescribers prior to changes to the SPC and that the main change to the prescribing information was the inclusion of a rare, albeit serious, adverse event with an incidence of greater than or equal to 1/10,000 and less than 1/1000, GlaxoSmithKline did not believe that either patient safety or confidence in the pharmaceutical industry had been compromised.

However, there was an oversight by an individual within GlaxoSmithKline, who did not create job bags for new advertisements with the updated prescribing information. This person had now been retrained and all others with this responsibility had been reminded of the importance of following the established process. This was an isolated incident; the prescribing information on all other promotional material created since August 2006 was current.

GlaxoSmithKline sincerely regretted this incident and submitted that when it had been brought to its attention by a competitor, it rapidly ascertained the scope of the problem and took immediate action to remedy it. GlaxoSmithKline was confident that it had a robust system in place and had demonstrated this in the course of this response. As such GlaxoSmithKline denied a breach of either Clause 9.1 or Clause 2. GlaxoSmithKline detailed the differences between the April and August prescribing information.

PANEL RULING

The Panel noted that out of date prescribing information had been used for approximately three months; the information given had not referred to macular oedema as a serious but rare side effect. Given the theoretical implications for patient safety the Panel ruled a breach of Clause 4.1 of the Code.

The Panel considered that high standards had not been maintained and a breach of Clause 9.1 of the Code was ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use.

Proceedings commenced	**29 November 2006**
Case completed	**16 January 2007**