CASE AUTH/2336/7/10

ANONYMOUS MEDICAL CONTRACTOR v GLAXOSMITHKLINE

Alleged unprofessional promotional practices

An anonymous and uncontactable medical contractor providing compliance services to pharmaceutical companies, including GlaxoSmithKline UK, alleged the following unprofessional practices within GlaxoSmithKline's respiratory and allergy therapy area:

1 Regular references to the regulatory authorities including the Medicines and Healthcare products Regulatory Agency (MHRA).

2 Use of the word 'new' for Avamys for more than a year.

3 No prescribing information for the products promoted on the health professional website.

4 Poor training of medical representatives and the setting of unrealistic targets for Rupafin, manipulating representatives into various target driven, unethical practices.

The detailed response from GlaxoSmithKline is given below.

The Panel noted that a Seretide leavepiece included the claim 'To aid compliance with the concomitant use of ICS [inhaled corticosteroid] and LABA [long-acting beta agonist], a combination inhaler should be used when appropriate (MHRA Drug Safety update)[4]'. Reference 4 given on the last page also referred to the MHRA as did reference 13 on the last page of the detail aid in support of a similar claim. The Panel thus ruled that the detail aid and the leavepiece were each in breach of the Code.

The Panel noted that promotion of Avamys started on 2 February 2009. An email instructing representatives to stop using current materials, sent on 4 February 2010 referred to immediately recalling certain items that no longer complied with the Code because of the use of the word 'new'. Material describing Avamys as new had not been recalled until 4 February 2010 and so in that regard it had been used for more than twelve months. Thus the Panel ruled a breach of the Code.

The Panel noted that with regard to the prescribing information on health professional websites the complainant had not provided any detail or examples of where prescribing information had not been provided. The Panel noted that material provided by GlaxoSmithKline showed that prescribing information was provided as a link on the website pages. On the basis of the information before it, the Panel ruled no breach of the Code.

The Panel noted that detailed training was provided for representatives promoting Rupafin. No breach of the Code was ruled.

The Panel noted GlaxoSmithKline's submission that its targets for representatives were ambitious but achievable. The Panel noted that no information had been provided by the complainant about what was unrealistic about the targets nor about the representatives' alleged target driven, unethical practices. The Panel decided that on the basis of the information before it there was no breach of the Code.

The Panel noted its rulings above and did not consider that overall GlaxoSmithKline had failed to maintain a high standard; no breach of the Code was ruled.

An anonymous and uncontactable medical contractor providing compliance services to pharmaceutical companies, including GlaxoSmithKline UK Ltd, complained about the promotional practices of GlaxoSmithKline.

COMPLAINT

The complainant stated that it would be a gross failure in the discharge of their professional duties if they failed to call to the Authority's attention the following unprofessional practices within GlaxoSmithKline's respiratory and allergy therapy area:

1 Regular references to the regulatory authorities including the Medicines and Healthcare products Regulatory Agency (MHRA) in all promotional items/materials for Seretide, Avamys, Rupafin and other branded products in the therapy area. This practice had been on-going since 2008 until the present.

2 Continued use of the word 'new' for Avamys despite it having been marketed for more than a year.

3 Non inclusion of prescribing information for the products promoted on the health professional website.

4 Poor training of medical representatives and the setting of unrealistic targets for Rupafin thereby placing commercial interests above ethics with the resultant manipulation of representatives into various target driven, unethical practices.

The complainant stated that this should be treated as an anonymous complaint, made in good faith to protect the reputation of the pharmaceutical companies and to protect public safety, as they

were currently contracted to GlaxoSmithKline where resistance to clinical governance and compliance remained very strong.

When writing to GlaxoSmithKline, the Authority asked it to respond in relation to Clauses 4.1, 7.11, 9.1, 9.5, 15.2, 15.4, 15.9 and 16.1 of the Code.

RESPONSE

GlaxoSmithKline noted that the introduction to the Constitution and Procedure stated:

> 'A complainant has the burden of proving their complaint on the balance of probabilities. Anonymous complaints are accepted and like all complaints are judged on the evidence provided by the parties. The weight to be attached to any evidence may be adversely affected if the source is anonymous and thus in some instances it will not be possible for such a complaint to proceed.'

GlaxoSmithKline asked the Authority to consider, given that no evidence was provided, whether it had a case to answer.

GlaxoSmithKline took its responsibility to ensure patient safety and compliance with all relevant ethical and regulatory codes very seriously and it strongly refuted any accusation that it had done otherwise. GlaxoSmithKline's proactive approach to compliance and its ethical stance was reflected in its record of inter-company and Authority complaints over the past few years.

GlaxoSmithKline had an open culture where the raising of ethical and compliance concerns was welcomed and where final signatories took their responsibilities very seriously. It was disappointed that someone employed to raise such concerns and to ensure compliance with the Code did not think it appropriate to do so directly with GlaxoSmithKline. A survey conducted in late 2009 indicated that the vast majority of employees understood what constituted ethical business practice and conduct in their job; considered that their working environment encouraged ethical behaviour, even in the face of pressures to meet business objectives, and that department leaders created an atmosphere of trust in which concerns could be raised.

Notwithstanding the above, in the spirit of the Code, GlaxoSmithKline responded to each of the points raised.

1 References to the regulatory authorities including the MHRA

GlaxoSmithKline refuted the allegation that all materials for Seretide, Avamys and Rupafin contained regular, or any other, references to regulatory agencies as evidenced by copies of currently used versions of the detail aids for each of the three products. Therefore GlaxoSmithKline denied a breach of Clause 9.5.

In the spirit of transparency, GlaxoSmithKline noted the following items:

- Reactive supplementary Seretide detail aid (ref SFL/DAP/09/42343/1) which featured the following claim: 'To aid Compliance with the concomitant use of inhaled corticosteroids and LABA [long-acting beta agonist], a combination inhaler should be used where appropriate'. This was supported by information provided in the publication 'Drug Safety Update' which was listed in the reference section as the 'MHRA Drug Safety Update. Volume 2, issue 12 July 2009'. This item was to respond to questions that might arise during a sales call.

- Seretide leavepiece (ref SFL/LVF/09/34470/2) where the same publication (Drug Safety Update) was listed within the body of the item as the 'MHRA Drug Safety Update'. This item was withdrawn 17 September 2009, two months after release due to the inclusion of 'MHRA' within the body of the item, even though the reference was to the MHRA Drug Safety Update publication and not the MHRA *per se*.

2 Use of the word 'new'

Avamys received its marketing authorization in January 2008. However, it was not available in the UK because GlaxoSmithKline did not market or distribute it until late 2008. Avamys was launched in the UK in February 2009, representatives were trained in the second half of January 2009 and the product was launched to the medical press on 9 February 2009. Due to the availability of the product licence, representatives were able to promote the product from the start of February 2009.

GlaxoSmithKline provided a copy of the current detail aid for Avamys, which was used from April 2010 and did not use the word 'new'.

In the spirit of transparency GlaxoSmithKline included information which outlined the communications associated with the launch of Avamys and the withdrawal of materials used in the first year that Avamys was marketed in the UK. All promotional staff were emailed on 4 February 2010 and asked to immediately stop using their current materials and return them for destruction. Replacement materials that did not use the word 'new' were provided later that week (Avamys detail aid dated January 2010). GlaxoSmithKline believed that the action it had taken resulted in continued compliance with Clause 7.11, which required that 'new' must not be used to describe any product that had been generally available for more than 12 months.

Due to the documented actions taken and materials provided, in which 'new' was not used, GlaxoSmithKline did not believe that it was in breach of Clause 7.11.

In response to a request for further information

GlaxoSmithKline stated that Avamys was launched internally, to representatives, on Thursday, 29 January 2009 after the product training, which took place earlier that week. That was why Avamys was referred to as having reached its first birthday on 29 January 2010 in the 'Recall of Avamys Campaign Materials' letter sent with the initial response.

Promotion could start Friday, 30 January when the representatives returned to their regions after the training meeting, with the majority of relevant representatives fully engaged in Avamys promotional activities on Monday 2 February 2009. The press release was issued on Monday 9 February 2009.

Promotional activities were mainly directed at GPs and pharmacists.

3 Prescribing information on health professional websites

GlaxoSmithKline was unsure as to which specific websites were being referred to. However, it provided copies of screen shots of its health professional website (http://hcp.gsk.co.uk/) for Seretide, Avamys and Rupafin. This website provided information based on the summary of product characteristics (SPC) on all its products including links to the SPC, patient information leaflet and the prescribing information for all medicines promoted by GlaxoSmithKline. GlaxoSmithKline provided copies of the relevant initial web pages and the prescribing information pages and noted the clear link to the relevant prescribing information. GlaxoSmithKline therefore denied a breach of Clause 4.1.

4 Training of medical representatives and targets for Rupafin

GlaxoSmithKline viewed the training of all staff involved with any medicine as critical to the success of the medicine and to relationships it had with its customers and the care they offered to their patients. This included clear and comprehensive training of relevant staff such that health professionals could be informed about the appropriate use of GlaxoSmithKline medicines in relevant patients. The Rupafin (rupatadine) training was composed of the following:

- Distance learning using a training manual with support and assessment of knowledge by field trainers.
- Regional road shows – one day workshops in all regions to consolidate distance learning (September 2009). This included a examination.
- Rolling diary of 5 day training, week starting 28 September 2009 for Rupafin and Avamys, as both products would be detailed by the same representatives – intended for new representatives and those that required refresher training.
- Post regional road show evaluation to assess level of satisfaction with the content and format of the regional conference.

As part of this comprehensive training plan, the targets for the brand and individuals were discussed. The targets were discussed down to an individual level, with opportunity for challenge if required. Given the market for anti-histamines and the way GlaxoSmithKline intended to position Rupafin, GlaxoSmithKline believed that the targets were ambitious but achievable and did not create any incentives that were counter to maintaining the highest ethical standards, which GlaxoSmithKline believed its representatives operated to at all times.

In response to a request for further information GlaxoSmithKline provided selected slides from the regional Rupafin road show training session for representatives one of which presented the Rupafin targets for 2009-2013 (targets had been revised for 2010-2013 this year). Another slide showed the Rupafin sales target for the final quarter of 2009. A third slide detailed the weighting of a representative's short term reward from Rupafin sales.

GlaxoSmithKline submitted that the targets set for the sales team and for individuals were not unrealistic or excessive or likely to encourage unethical behaviour. Irrespective of the targets set for any medicine, GlaxoSmithKline continued to believe its representatives operated to high ethical standards.

GlaxoSmithKline submitted that the documents provided demonstrated that the training plan was comprehensive, well planned and well monitored. This included the clear communication of the relevant therapy area, medicine and sales technique information as well as assessment and seeking of opinion of the representatives that had been trained. This was in addition to the annual Code training and GlaxoSmithKline's culture of ethical compliance that was in place for all promotional representatives.

GlaxoSmithKline remained committed to encouraging a culture of quality and compliance within the company. It trusted the Authority would agree that it had maintained the highest ethical standards in all activities carried out by the respiratory and allergy team. GlaxoSmithKline therefore believed that it was not in breach of Clauses 4.1, 7.11, 9.5, 15.2, 15.4, 15.9, 16.1 and 9.1.

GlaxoSmithKline again queried whether this complaint should proceed at all given the lack of evidence to support the anonymous medical contractor's serious allegations.

PANEL RULING

The Panel noted GlaxoSmithKline's concerns about the lack of evidence from the anonymous complainant. Nevertheless, a complaint had been made from which it appeared that a company might have breached the Code and, as set out in Paragraph 5.1 of the Constitution and Procedure, it needed to be considered bearing in mind that the

complainant had the burden of proving their complaint on the balance of probabilities.

1 References to the MHRA

The Panel noted that a Seretide leavepiece included the claim 'To aid compliance with the concomitant use of ICS [inhaled corticosteroid] and LABA, a combination inhaler should be used when appropriate (MHRA Drug Safety Update)[4]'. Reference 4 given on the last page also included mention of the MHRA.

The Seretide detail aid included the claim 'To aid compliance with the concomitant use of inhaled corticosteroids and LABA, a combination inhaler should be used when appropriate[13]'. Reference 13 given on the last page included mention of the MHRA.

Clause 9.5 stated that promotional material must not include **any** (emphasis added) reference to, *inter alia*, the MHRA, unless this was specifically required by the MHRA. The Panel thus ruled that the detail aid and the leavepiece were each in breach of Clause 9.5. The Panel noted that the leavepiece had already been withdrawn because of the reference to the MHRA.

2 Use of word the word 'new'

The Panel noted that promotion of Avamys started on 2 February 2009. The email instructing representatives to stop using current materials, sent on 4 February 2010 at 18:29, referred to immediately recalling certain items that no longer complied with the Code. The email stated that the issue related to the use of the word 'new' that appeared on certain items. Material describing Avamys as new had not been recalled until after the close of business on 4 February 2010 and so in that regard it had been used for more than twelve months. Thus the Panel ruled a breach of Clause 7.11.

3 Prescribing information on health professional websites

The Panel noted that the complainant had not provided any detail or examples of where prescribing information had not been provided. The Panel noted that material provided by GlaxoSmithKline showed that prescribing information was provided as a link on the website pages. On the basis of the information before it, the Panel ruled no breach of Clause 4.1.

4 Training of medical representatives and targets for Rupafin

The Panel noted that detailed training was provided for representatives promoting Rupafin. No breach of Clause 16.1 was ruled.

With regard to targets for such representatives the Panel noted GlaxoSmithKline's submission that its targets were ambitious but achievable. The targets had been revised this year. The Panel noted that no information had been provided by the complainant about what was unrealistic about the targets nor about the alleged target driven, unethical practices by representatives. The Panel decided that on the basis of the information before it there was no breach of Clauses 15.2, 15.4, and 15.9 and ruled accordingly.

The Panel noted its rulings above and did not consider that overall GlaxoSmithKline had failed to maintain a high standard; no breach of Clause 9.1 was ruled.

Complaint received **27 July 2010**

Case completed **20 September 2010**