CASE AUTH/2012/6/07

GLAXOSMITHKLINE v TAKEDA

Competact mailer

GlaxoSmithKline alleged that in a Competact (pioglitazone and metformin) mailer, produced by Takeda, the claim 'Unlike other glitazone combination therapies, Competact costs LESS to prescribe than its constituent parts' was untrue. When the mailer was issued in January 2007 GlaxoSmithKline's product Avandamet (rosiglitazone and metformin) also cost less than its constituent parts.

GlaxoSmithKline further alleged that, despite inter-company dialogue on the matter, the mailer was used up until May 2007. Companies knowingly continuing to distribute incorrect information brought discredit upon and reduced confidence in the industry.

The Panel considered that the claim at issue was misleading and unfair as alleged. When the mailing was sent in January Avandamet also cost less than its component parts. A breach of the Code was ruled.

The Panel noted that the mailing had been sent on 2 January 2007 when a new Drug Tariff price for generic metformin had come into effect thus rendering the claim misleading and unfair. The Panel considered that by not checking the details in the January Drug Tariff prior to sending the mailing, Takeda had not maintained a high standard. A breach of the Code was ruled.

The Panel considered that in these circumstances the continued use of a claim acknowledged in inter-company correspondence to be in breach of the Code brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

GlaxoSmithKline UK Limited complained about a mailer (ref CM060811) for Competact (pioglitazone and metformin) produced by Takeda UK Limited. GlaxoSmithKline produced Avandamet (rosiglitazone and metformin).

COMPLAINT

GlaxoSmithKline stated that the mailing included the claim that Competact, one of two glitazone/metformin fixed-dose combination products on the UK market, and not the other, Avandamet, cost less than its component parts.

Fixed-dose combination preparations were the subject of some scrutiny by prescribers and prescribing advisers, as the cost to the NHS needed to be measured against the cost of their component parts prescribed separately. In this area this was especially pertinent as the price of generic metformin changed frequently according to market forces. The price of all reimbursable products was given in the Drug Tariff which was updated monthly, usually on the first of the month, with immediate effect.

The mailer in question had a date of preparation of January 2007, and GlaxoSmithKline understood from Takeda that it was first posted on 2 January to customers in several areas of the UK. GlaxoSmithKline was also aware of its use on several occasions across different parts of the UK since January.

In the mailer Takeda claimed that 'Unlike other glitazone combination therapies, Competact costs LESS to prescribe than its constituent parts'. This was not the case when the mailer was issued as Avandamet cost less than its single-constituent components.

During the inter-company dialogue Takeda had agreed that it used the Drug Tariff reimbursement price as the basis for the claim but had argued that the claim was correct up until immediately before the issue of the item. Takeda was correct in stating that the claim was accurate on 31 December 2006.

GlaxoSmithKline noted that apart from the three-month period from 1 October to 31 December 2006, during the twelve months, 1 June 2006 to 31 May 2007 inclusive, preceding this exchange, both Avandamet and Competact had cost the NHS less than their component parts prescribed separately. Takeda UK knew that the price of generic metformin had a recent history of being liable to fluctuation and that a new Drug Tariff price list would be published at the beginning of January. Despite this it sent out a mailer disparaging a competitor on the first working day of January without making adequate efforts to ensure that the claim was still correct and up-to-date.
The prominent statement that the date of preparation of the mailer was January 2007 reinforced the impression that the claim was correct in relation to the January 2007 Drug Tariff. Given the scrutiny of fixed dose combinations as mentioned above, once Takeda knew its claim was invalid it should have issued a corrective notice to all recipients of the mailer without waiting for a complaint from GlaxoSmithKline.

Copies of the online notification of changes to the Drug Tariff in January 2007, a record of the prices of generic metformin during the period June 2006 to June 2007, and a cost comparison of Avandamet versus its separate components for January 2007 were provided.

GlaxoSmithKline stated that with regard to the mailer at issue, despite extensive inter-company dialogue starting on 19 April it was aware of continued use of the mailer throughout the year, in a variety of locations

throughout the UK, up until May, in areas as widespread as Greater Manchester, Billericay, and Fife in Scotland. Takeda stated on 2 May that it was a one off mailer to a small distribution in one area only and was correct when it was mailed (this was not the case). However, on 16 May Takeda agreed in principle to issue a corrective notice to all the recipients of the mailer.

GlaxoSmithKline had asked Takeda to send that corrective letter to all recipients by 15 June with a copy to GlaxoSmithKline and notification to it that the corrective letter had been sent by 15 June.

In accordance with Code of Practice guidelines GlaxoSmithKline had set reasonable deadlines for completion of each stage of the process for reaching the agreed resolution of this issue. One month was more than adequate time to distribute a corrective letter for a mailing that had been in circulation since January 2007. This deadline had now passed without apology or explanation from Takeda.

A mailer such as the one at issue was a powerful way to communicate sensitive issues such as price. Recipients would expect that the information was factually correct and up-to-date. Companies mailing incorrect information and knowingly continuing to distribute it, brought discredit on the industry as a whole and served to reduce confidence in the industry.

GlaxoSmithKline alleged that the mailer was in breach of Clauses 7.2 and 7.3 of the Code. Takeda's failure to recognise its error and take timely corrective action with or without GlaxoSmithKline's intervention made its actions also in breach of Clause 9.1 and likely Clause 2.

While GlaxoSmithKline knew that the Panel had no power to impose sanctions on companies, it would urge that it considered in its ruling the impact of such continued activity in breach of the Code, and judge whether any further actions should be considered to redress the circulation of this factually inaccurate information.

RESPONSE

Takeda submitted that the mailer in question reminded prescribers about the efficacy and cost of Competact, which had recently been launched in the UK. GlaxoSmithKline initiated inter-company correspondence about the claim 'Unlike other glitazone combination therapies, Competact costs LESS to prescribe than its constituent parts' in April 2007 when both Competact and Avandamet were cheaper than their constituent parts. It became apparent that January Drug Tariff prices had changed and that Competact was £3.23 cheaper than its constituent parts, and Avandamet was 14p cheaper than its constituent parts. However when the piece was developed, Avandamet was 13p more than its component parts. Whilst acknowledging the error in pricing, Takeda considered this error was relatively small in that Avandamet was inadvertently portrayed as being more expensive than the cost of its component parts, arising through changes in the metformin price generated by the NHS Drug Tariff, unbeknown to Takeda. Importantly this error portrayed more a commercial issue, rather than jeopardising patient safety, as suggested by GlaxoSmithKline in its initial complaint, and did not make inappropriate clinical claims. Takeda had stopped using this claim and reassured GlaxoSmithKline as part of the inter-company dialogue.

Takeda had agreed to GlaxoSmithKline's request to send a corrective letter to all recipients of the mailer. Takeda had not agreed to GlaxoSmithKline's request to see the distribution list and review the letter prior to mailing. The last contact Takeda had from GlaxoSmithKline suggested that it had accepted Takeda's agreement. GlaxoSmithKline stated 'I trust that your undertaking will be to distribute the corrective letter to all lists who received the mailing – as you will not provide evidence of this – if GSK find that a corrective letter has not been received by one of the original recipients we will progress this complaint to the PMCPA. Once the above has been adhered to GSK will consider the matter closed'.

Takeda had done as agreed and sent the corrective mailer to all recipients of the original one. Takeda was in fact waiting to receive its final copies for its records and in order to send one to GlaxoSmithKline, when it received an email from GlaxoSmithKline stating that it had escalated this matter to the Authority. Takeda immediately emailed back to state that it considered this action inappropriate. The complaint to the Authority was dated the same day as Takeda had emailed GlaxoSmithKline as detailed above. This showed unwillingness on GlaxoSmithKline's part to resolve this matter at the inter-company level.

The mailer in question was produced shortly after the launch of Competact in the UK and was intended to remind prescribers that an advantage of Competact was that it was actually priced less than the sum of the cost of the constituent parts, and hence might be able to save the prescriber money.

Takeda had a different sales force structure to most pharmaceutical companies and as part of its regionalised structure each regional account director was able to develop materials for their own specific region and then have these approved by the usual certification process. The mailer in question was developed specifically for one regional account director. When GlaxoSmithKline raised its concern with Takeda its records showed that this was the only area that this was used in. Takeda subsequently found that it was used in several other areas but that this had not been recorded adequately in Takeda's approval system. Takeda acknowledged this to GlaxoSmithKline through inter-company dialogue when Takeda agreed to send a corrective mailer in all areas that the original mailer was sent. Furthermore, Takeda had ensured that its systems were robust in order to prevent a similar situation happening again.

The mailer was not mailed to anyone after this matter was identified. A revised version of the same mailer

was produced with the claim at issue deleted. GlaxoSmithKline had alleged that the item was in use in May; however this was not the case. The item was a mailer and as such was a one-off item that was mailed on a particular date. It was not an item that Takeda's regional account directors carried with them and distributed. At the time of writing this response GlaxoSmithKline had again only the day before reported that this letter was in use in May 2007. Takeda had checked its records and informed GlaxoSmithKline that this was not the case. Whilst Takeda awaited a copy of the mailer and evidence of the date it was in use, it had instigated a full investigation into the matter with its mailing house.

When this item was developed the price of generic metformin (£2.13 for 84 x 500mg tablets) had been stable for the whole time that Takeda had monitored it in preparation for the launch of Competact in the UK (October 2006 onwards). Takeda had not monitored the generic price before this time as the product was not licensed and hence Takeda was not developing materials.

This mailer was reviewed before Christmas but was not printed and subsequently posted until the first week in January. The date of preparation was changed to reflect the posting date in January without the generic prices being rechecked and this was an inadvertent process error. Takeda had fully investigated how this happened and had put processes in place to ensure it could not happen again. Hence Takeda did not know that the generic price for metformin had increased (to £2.33 for 84 x 500mg tablets) in January 2007 until GlaxoSmithKline raised this matter with it in April. This increase in price of metformin made Avandamet 14p cheaper than its constituent parts whereas for Competect the price difference was £3.23.

When this matter was raised by GlaxoSmithKline, Takeda gave a written undertaking to ensure that this claim was not in use on other materials and to ensure that it would not be used again. At the same time Takeda agreed to send a corrective mailer to all recipients of the original mailer.

Takeda accepted that an error had been made and it had taken this matter very seriously and had already put a process in place to ensure that would not occur again. However as stated this matter had already been resolved at the inter-company level and hence Takeda did not consider that it was appropriate for this to be forwarded to the Authority. Takeda refuted the allegation that it had breached Clauses 9.1 and 2.

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Following receipt of the response from Takeda regarding the above, the Director was concerned that GlaxoSmithKline's complaint did not meet the requirements of Paragraph 5.2 of the Constitution and Procedure. Paragraph 5.2 states, *inter alia*, that a complaint from a pharmaceutical company will be accepted only if the Director is satisfied that the company concerned has previously informed the company alleged to have breached the Code that it proposed to make a formal complaint and offered inter-company dialogue at a senior level in an attempt to resolve the matter, but that this offer was refused or dialogue proved unsuccessful.

In its response Takeda stated that it acknowledged its error, had stopped using the claim at issue and, as part of inter-company dialogue, reassured GlaxoSmithKline in this regard. It thus appeared that the requirements of Paragraph 5.2 had not been met ie the matter regarding the use of the claim at issue had been resolved. Takeda was longer using the claim 'Unlike other glitazone combination therapies, Competact costs less to prescribe than its constituent parts'.

GlaxoSmithKline had asked Takeda to take corrective action but this had not been done by the time GlaxoSmithKline sent its complaint to the Authority. Nonetheless, the claim at issue was no longer in use by Takeda and so in that respect the matter had been resolved. The Director could not accept a complaint on the basis that Takeda had not carried out sanctions requested by GlaxoSmithKline.

The Authority so informed GlaxoSmithKline.

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A further letter was received from Takeda stating that its investigation referred to in its response was now completed. GlaxoSmithKline informed Takeda on Monday 9 July that the mailer at issue was in use in a specific area of the UK. At that time Takeda checked its records and spoke to its mailing house and confirmed that this could not be correct as the mailer had not been posted since February.

GlaxoSmithKline had named the region and also the sales person alleged to be responsible. On the basis of this information a full investigation into the matter found a member of the sales team had gone outside of company standard operating procedures (SOPs) and guidance and had arranged for the mailer to be reprinted by a local printer and mailed in his region. This was absolutely unacceptable and had left Takeda in a regrettable situation whereby it had provided information to GlaxoSmithKline in good faith, only to then find that action had been taken by an individual which contradicted the information provided.

The investigation and subsequent disciplinary process was now underway with this individual. Takeda took such breaches of company SOPs and of the Code very seriously indeed.

Takeda had also issued a statement to all customer-facing staff on this matter and required each to sign the document to show that they had read and understood the instruction. It would also provide the additional training on this matter at the next company meeting.

Takeda was extremely disappointed that this had happened and that as a result of one individual's actions the company had been compromised. Takeda hoped that this letter demonstrated the seriousness of

this matter to the company and that appropriate action had been taken.

In response to a request for further information Takeda advised that the mailer was last sent out on 16 May.

PANEL RULING

The Panel noted that during inter-company correspondence with GlaxoSmithKline, Takeda had stated that the mailer was a one-off item. It had been posted in the first week of January. In its response to the Authority, Takeda again noted that the mailer was a one-off and submitted that it had stopped using the claim and that the mailer had not been sent to anyone after the matter was identified – which presumably was in April 2007 when inter-company correspondence began. Takeda denied that the mailer had continued to be used, as alleged by GlaxoSmithKline, in May 2007. However, in a subsequent letter to the Authority, Takeda stated that this was not so. Although not sent via the company's mailing house, a representative had had the mailing reprinted locally and mailed in his region. The Director considered that the continued use of the mailer meant that inter-company dialogue had been unsuccessful and therefore the complaint should proceed.

The Panel considered that the claim at issue 'Unlike other glitazone combination therapies, Competact costs LESS to prescribe than its constituent parts' was misleading and unfair. When the mailer was sent in January Avandamet also cost less than its component parts. Breaches of Clauses 7.2 and 7.3 were ruled.

The Panel noted that the mailer had been sent on 2 January when a new Drug Tariff price for generic metformin had come into effect thus rendering the claim misleading and unfair. The Panel considered that by not checking the details in the January Drug Tariff prior to sending the mailer, Takeda had not maintained a high standard. A breach of Clause 9.1 was ruled.

The Panel considered that in these circumstances the continued use of a claim acknowledged in inter-company correspondence to be in breach of the Code brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel noted that Takeda had been seriously let down by one of its representatives. As the individual concerned had used a local printer to reproduce the mailer, Takeda had no record of its continued use and in this regard had, at first, given misleading information to both GlaxoSmithKline and the Authority. It appeared that until the identity of the individual had been revealed, Takeda had been unable to properly investigate the matter. Although seriously concerned about what had happened the Panel considered that, in the circumstances, it would not report Takeda to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure.

Complaint received	**21 June 2007**
Case completed	**3 September 2007**