CASE AUTH/2192/12/08

VOLUNTARY ADMISSION BY PFIZER

Lipitor Journal advertisement

Pfizer voluntarily admitted that it had breached the undertaking and assurance which it had given in Case AUTH/2093/1/08 in that the Lipitor fireman journal advertisement, found in breach of the Code in May 2008, had been published in the November 2008 edition of Practitioner.

The detailed response from Pfizer is given below.

The Authority's Constitution and Procedure provided that the Director should treat an admission as a complaint if it related to a potentially serious breach of the Code or if the company failed to take appropriate action to address the matter. A breach of undertaking was a serious matter and the admission was accordingly treated as a complaint.

The Panel noted that the undertaking in Case AUTH/2093/1/08 was signed on 15 May 2008. The advertisement had re-appeared in the Practitioner, November 2008. The Panel ruled a breach of the Code which was not appealed by Pfizer.

The Panel noted a 'Withdrawal of Advertisement' form sent from Pfizer to its agents referred to the 'Lipitor Fireman advert' with a reference number LIP 2933. The form stated 'Please destroy all copies of the advertisements above. Original artwork may be kept but must be stored electronically with sufficient safeguards to ensure that it cannot be used accidentally. We suggest creating a folder called "Withdrawn materials: not to be used".' Recipients were to sign the form and return it to the Lipitor brand manager to confirm that they had complied with the notice. The form stated that the advertisements must not be used again.

The Panel was concerned that the form did not state why the advertisement had to be withdrawn. In the Panel's view the knowledge that an advertisement was in breach of the Code would have emphasised the urgency of complying with the withdrawal request. The form only listed one advertisement (ref LIP 2933) and did not alert the reader that there might be a number of executions of the same advertisement. The reader had no way of knowing how many advertisements had to be destroyed.

Further, the agencies were asked to destroy the advertisements but advised that they might keep the original artwork. The way such artwork was kept was left up to the agency with a suggestion that it create a folder called 'Withdrawn materials: not to be used' and that there be sufficient safeguards to prevent accidental use.

Finally the form required the recipient to confirm that they had complied with the notice. In the Panel's view the recipients should have been required to confirm that they had destroyed the advertisements, giving details of each reference number, and to give details as to their arrangements for storing the original artwork.

The Panel considered that if pharmaceutical companies were to allow agencies to store original artwork that was not to be used then they must ensure, and take responsibility for, the agencies creating a secure archive for such material. To merely suggest on a form the creation of a folder called 'Withdrawn materials: not to be used' was unacceptable.

The Panel noted that a letter from Pfizer's healthcare media company stated that '… [Pfizer's media buyer] instructed [Pfizer's healthcare media company] not to run the 'Fireman' advertisement due to an out of date product [prescribing information]. Whilst this was forwarded to our production department, there has been a breakdown in communication'. The Panel noted that out of date prescribing information was not at issue in Case AUTH/2093/1/08.

Overall the Panel did not consider that Pfizer had a sufficiently robust procedure for ensuring that material ruled in breach of the Code was not re-used. Agencies were not told why advertisements had to be withdrawn or given precise enough instructions about how many advertisements had to be withdrawn; they were allowed to make their own arrangements for secure storage of original artwork. On balance the Panel considered that high standards had not been maintained. A breach of the Code was ruled which was appealed by Pfizer.

Upon appeal the Appeal Board noted that Pfizer's 'Withdrawal of Advertisement' form stated clearly at the top that 'The following advertisements must be removed from any media in which they appear immediately. These advertisements must not be used again. The items affected are: …'. This was followed by a description of the advertisement (Lipitor fireman advertisement) a reference number, LIP 2933 and the section listing the name of the journals where it appear referred to all press as indicated in an attached document or similar. The form then stated 'Please destroy all copies of the advertisements above. Original artwork may be kept but must be stored electronically with sufficient safeguards to ensure that it cannot be used accidentally. We suggest creating a folder called "withdrawn materials: not to be used"'. The form stated that it must be signed by the recipient to confirm that they had complied with the notice and that the advertisements in the journals

mentioned should not appear after 8 May 2008. The forms were signed and returned by the recipients.

The Appeal Board considered that the form made it clear that copies of the advertisement at issue were to be destroyed and not used again.

The Appeal Board noted that Pfizer's media buyer had confirmed with Pfizer's healthcare media company that it would not run the Lipitor fireman advertisement again. The replacement advertisement for Lipitor had subsequently been published 34 times in October and November although not in Practitioner. The first Lipitor advertisement to appear in the Practitioner since May 2008 was in November when Pfizer's healthcare media company incorrectly published the fireman advertisement.

The Appeal Board considered that it might have been helpful if Pfizer had stated on its form that the advertisement was being withdrawn because it was in breach of the Code. Correspondence from Pfizer's healthcare media company indicated that the advertisement had been withdrawn due to out-of-date prescribing information.

Nonetheless the Appeal Board considered that Pfizer had taken reasonable steps to endeavour to comply with its undertaking; it had been badly let down by its healthcare media company. The Appeal Board did not consider in the circumstances that Pfizer had failed to maintain high standards and it thus ruled no breach of the Code.

The Panel considered that Pfizer had endeavoured to comply with its undertaking. Although company procedures could have been more robust the company was also let down by one of its agents. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 of the Code which was a sign of particular censure and reserved for such. No breach of the Code was ruled.

Pfizer Limited voluntarily admitted that it had breached the undertaking and assurance which it had given in Case AUTH/2093/1/08 in that the Lipitor fireman journal advertisement, found in breach of Clauses 7.2 and 7.10 of the Code in May 2008, had been published again.

COMPLAINT

Pfizer explained that when notified of the outcome of Case AUTH/2093/1/08 it had followed internal processes to prevent the fireman advertisement being published again. This included asking all of the parties involved to confirm that they had destroyed all existing copies. Contrary to Pfizer's instruction, the advertisement had inadvertently appeared in the November 2008 edition of Practitioner.

Pfizer explained that in late April it was informed that the advertisement had been found in breach of the Code; Pfizer then telephoned its media buyer, to instruct it to notify its clients that the advertisement should be withdrawn – an email to this effect, which was sent from Pfizer's media buyer on 30 April was provided. In reply to this email Pfizer's healthcare media company stated that the fireman advertisement would not be used again.

Written confirmation of the ruling was received on 8 May after which Pfizer followed stringent communication procedures to ensure that the fireman advertisement was withdrawn from circulation and destroyed. Pfizer's notification emails to it's media buyer, its creative design agency, and its European brand team were provided, along with the signed responses from each of them, which stated that all copies of the advertisement would be destroyed and never used again.

On 26 September, although Pfizer's creative design agency emailed Pfizer's healthcare media company to run the new Lipitor 'fisherman' advertisement in the November edition of Practitioner, and attached the PDF of the advertisement to the email, the healthcare media company nonetheless published the withdrawn fireman advertisement.

Immediately upon hearing about this, Pfizer investigated the matter fully and discussed the seriousness of it with all parties involved. The publishers, Pfizer's healthcare media company, had assumed full responsibility for the error which was a result of a communication error within its own production department, and had assured Pfizer that measures had been taken to prevent this situation reoccurring.

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The Authority's Constitution and Procedure provided that the Director should treat an admission as a complaint if it related to a potentially serious breach of the Code or if the company failed to take appropriate action to address the matter. A breach of undertaking was a serious matter and the admission was accordingly treated as a complaint. The Authority asked Pfizer to comment in relation to Clauses 2, 9.1 and 25.

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RESPONSE

Pfizer stated in reply that there was no information or evidence to add to its initial admission. It strongly believed that its actions confirmed that it had absolutely maintained high standards, adhered to its undertaking and not brought the industry into disrepute and therefore was not in breach of Clauses 2, 9.1 or 25.

PANEL RULING

The Panel considered that an undertaking was an

important document. It included an assurance that all possible steps would be taken to avoid similar breaches of the Code in future. It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that in Case AUTH/2093/1/08 the Lipitor fireman advertisement was ruled in breach of the Code. The Appeal Board considered that it exaggerated the urgency to prescribe which was incompatible with advice given to prescribers in the Lipitor summary of product characteristics (SPC). The undertaking was signed on 15 May 2008. The advertisement had re-appeared in the Practitioner, November 2008. The Panel ruled a breach of Clause 25.

The Panel noted a 'Withdrawal of Advertisement' form sent from Pfizer to its agents referred to the 'Lipitor Fireman advert' with a reference number LIP 2933. The form stated 'Please destroy all copies of the advertisements above. Original artwork may be kept but must be stored electronically with sufficient safeguards to ensure that it cannot be used accidentally. We suggest creating a folder called "Withdrawn materials: not to be used".' Recipients were to sign the form and return it to the Lipitor brand manager to confirm that they had complied with the notice. The form stated that the advertisements must not be used again. The Panel noted that the Pfizer European Brand Team who oversaw withdrawal of the advertisement from European Media with a UK circulation were provided with the form and an accompanying email which gave more details about the advertisement.

The Panel had a number of concerns about the form: The form did not state why the advertisement had to be withdrawn. In the Panel's view the knowledge that an advertisement was in breach of the Code would have emphasised the urgency of complying with the withdrawal request. The form only listed one advertisement (ref LIP 2933) and did not alert the reader that there might be a number of executions of the same advertisement (the advertisement at issue in Case AUTH/2093/1/08 had been ref LIP 2933e). The reader had no way of knowing how many advertisements had to be destroyed. In the Panel's view every reference code should have been listed.

Further, the agencies were asked to destroy the advertisements but advised that they might keep the original artwork. The Panel noted that the agency might own the original artwork. The way such artwork was kept was left up to the agency with a suggestion that it create a folder called 'Withdrawn materials: not to be used' and that there be sufficient safeguards to prevent accidental use.

Finally the form required the recipient to confirm that they had complied with the notice. In the Panel's view the recipients should have been required to confirm that they had destroyed the advertisements, giving details of each reference number, and to give details as to their arrangements for storing the original artwork.

The Panel considered that if pharmaceutical companies were to allow agencies to store original artwork that was not to be used then they must ensure, and take responsibility for, the agencies creating a secure archive for such material. To merely suggest on a form the creation of a folder called 'Withdrawn materials: not to be used' was unacceptable.

The Panel noted that a letter from Pfizer's healthcare media company stated that '…[Pfizer's Media Buyer] instructed [Pfizer's healthcare media company] not to run the 'Fireman' advertisement due to an out of date product [prescribing information]. Whilst this was forwarded to our production department, there has been a breakdown in communication'. The Panel noted that with regard to the matter at issue in Case AUTH/2093/1/08 out of date prescribing information was not a factor.

Overall the Panel did not consider that Pfizer had a sufficiently robust procedure for ensuring that material ruled in breach of the Code was not re-used. Agencies were not told why advertisements had to be withdrawn or given precise enough instructions about how many advertisements had to be withdrawn. Agencies were allowed to make their own arrangements for secure storage of original artwork. On balance the Panel considered that high standards had not been maintained. A breach of Clause 9.1 was ruled which was appealed by Pfizer.

The Panel considered that Pfizer had endeavoured to comply with its undertaking. Although company procedures could have been more robust the company was also let down by one of its agents. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 of the Code which was a sign of particular censure and reserved for such. No breach of Clause 2 was ruled.

APPEAL BY PFIZER

Pfizer noted that the Panel had considered that there was not a sufficiently robust procedure for ensuring that material ruled in breach of the Code was not re-used. As previously described, Pfizer had followed stringent communication procedures to ensure that the fireman advertisement was withdrawn from circulation and destroyed. The publisher had not followed clear and explicit instructions to destroy the advertisement. In support of this, the publishers, Pfizer's healthcare media company, assumed full responsibility for the error, which was a result of a communication error within its production department.

The fireman advertisement was found in breach of Clauses 7.2 and 7.10 of the Code in May 2008 (Case AUTH/2093/1/08). Following that, emails of 12 May from the Lipitor brand manager to Pfizer's media buyer, Pfizer's creative design agency and the Pfizer european brand team, informed them of the

withdrawal of the advertisement. Each of these parties in return signed the 'Withdrawal of Advertisement' form which stated that all copies of the fireman advertisement must be destroyed and never used again. Following this, the advertisement was withdrawn from circulation and substituted with other advertisements.

Pfizer noted, in support of the robustness of its internal processes, the number of times the correct Lipitor advertisement (the fisherman) was published by other publishers in journals during the period of October to November 2008. This was confirmed by a media schedule and an email from Pfizer's media buyer (provided) which stated that the fisherman advertisement was published 34 times in October and November prior to the publication of the wrong advertisement (the fireman) by Pfizer's healthcare media company in November. The fact that the correct version of the advertisement had been published so many times previously made it difficult for Pfizer to anticipate this error; Pfizer felt very badly let down by its healthcare media company. This was especially so as it also had evidence that its creative design agency explicitly instructed Pfizer's healthcare media company via email to run the new Lipitor advertisement and attached the pdf of the correct fisherman advertisement to this email. The correct Lipitor advertisement was immediately distinguishable from the one found in breach of the Code as it featured a fisherman as opposed to a fireman.

Pfizer noted that the Panel had four main concerns about the 'Withdrawal of Advertisement' form.

i) The form did not state why the advertisement had to be withdrawn.

Whilst Pfizer agreed that the form could be improved upon to include a reason for withdrawal, it referred to a previous case, Case AUTH/2048/9/07 which bore many similarities to the current case. The case involved a voluntary admission from Grünenthal that it had breached the undertaking and assurance in relation to a journal advertisement for Versatis (lidocaine medicated plaster). A reason for withdrawal of the advertisement was not mentioned in the correspondence with the publishers. Despite this omission, the Panel did not rule a breach of Clause 9.1.

ii) The form only listed one advertisement (ref LIP 2933) and did not alert the reader that there might be a number of executions of the same advertisement.

Again Pfizer agreed with the Panel's suggestion as to how it could improve on making its instructions for withdrawal of advertisements more explicit to the reader. However, it was reasonable to assume that the reference to LIP 2933 would immediately alert the reader that all promotional materials bearing this code did not vary in content and were identical with the exception of the size. So whilst LIP 2933e was the journal advertisement complained about LIP2993a was an iteration of that advertisement which differed only in size to comply with the publishers' requirements.

iii) Agencies were allowed to make their own arrangements for secure storage of original artwork but the form did not require them to give details as to their arrangement for storing the original artwork.

Pfizer submitted that the form included the following statement: 'Original artwork may be kept but must be stored electronically with sufficient safeguards to ensure that it cannot be used accidentally. We suggest creating 'Withdrawn materials: not to be used'. Pfizer submitted that whilst it was responsible for communicating clearly to agencies the need to ensure that sufficient safeguards were put in place to ensure that withdrawn advertisements could not be used accidentally and even to suggest how this could be done, it could not take responsibility ultimately for the manner in which this was carried out and would have no grounds for enforcing a rule on this.

iv) The form required the recipient to confirm they had complied with the notice rather than confirm destruction of the material.

Pfizer noted that the form clearly stated that material must be destroyed and therefore confirmation of compliance with the notice meant compliance with everything stated in the notice.

Pfizer noted that in Case AUTH/2048/8/07 Grünenthal had not asked the publishers to confirm that the old version of advertisement had been destroyed. Despite this omission, the Panel did not rule a breach of Clause 9.1.

Pfizer submitted that it had, to the best of its abilities, taken all the steps required in its internal processes to comply with the undertaking signed in May 2008 and these processes were robust. This breach of undertaking had occurred because Pfizer's healthcare media company did not follow Pfizer's explicit instructions to destroy the fireman advertisement. As discussed in the previous case (Case AUTH/2048/8/07) although some improvements could be made to the 'Withdrawal of Advertisement' form, high standards had not been breached and therefore Pfizer was not in breach of Clause 9.1. Pfizer submitted that the rulings in these two cases were not consistent.

APPEAL BOARD RULING

The Appeal Board noted Pfizer's reference to Case AUTH/2048/8/07 but considered that it was not bound by the Panel's ruling in that case. Each case had to be considered on its own merits.

The Appeal Board considered that it was very important for the reputation of the industry that companies complied with their undertakings. Pfizer

had not appealed the Panel's ruling of a breach of Clause 25.

The Appeal Board noted that the 'Withdrawal of Advertisement' form sent by Pfizer to, *inter alia*, Pfizer's media buyer and Pfizer's creative design agency, stated clearly at the top that 'The following advertisements must be removed from any media in which they appear immediately. These advertisements must not be used again. The items affected are: …'. This was followed by a description of the advertisement (Lipitor fireman advertisement) a reference number, LIP 2933 and the section listing the name of the journals where it appear referred to all press as indicated in an attached document or similar. The form then stated 'Please destroy all copies of the advertisements above. Original artwork may be kept but must be stored electronically with sufficient safeguards to ensure that it cannot be used accidentally. We suggest creating a folder called "withdrawn materials: not to be used"'. The form stated that it must be signed by the recipient to confirm that they had complied with the notice and that the advertisements in the journals mentioned should not appear after 8 May 2008. The forms were signed and returned by the recipients.

The Appeal Board considered that the form made it clear that copies of the advertisement at issue were to be destroyed and not used again. The Appeal Board noted that Pfizer's media buyer had confirmed with Pfizer's healthcare media company that it would not run the Lipitor fireman advertisement again. The replacement advertisement for Lipitor had subsequently been published 34 times in October and November although not in Practitioner. The first Lipitor advertisement to appear in the Practitioner since May 2008 was in November when Pfizer's healthcare media company incorrectly published the fireman advertisement.

The Appeal Board considered that it might have been helpful if Pfizer had stated on its form that the advertisement was being withdrawn because it was in breach of the Code. Correspondence from Pfizer's healthcare media company indicated that the advertisement had been withdrawn due to out-of-date prescribing information.

Nonetheless the Appeal Board considered that Pfizer had taken reasonable steps to endeavour to comply with its undertaking; it had been badly let down by its healthcare media company. The Appeal Board did not consider in the circumstances that Pfizer had failed to maintain high standards and it thus ruled no breach of Clause 9.1. The appeal was successful.

Complaint received **15 December 2008**

Case completed **18 March 2009**