

# CEPHALON/DIRECTOR v PROSTRAKAN

## Promotion of Abstral

Cephalon alleged that an Abstral (sublingual fentanyl citrate) advertisement issued by ProStrakan which appeared in the BMJ 12 September 2009 was in breach not only of the undertaking given in Case AUTH/2207/2/09, but also in breach of that given in Case AUTH/2235/5/09.

As the complaint alleged a breach of the undertakings given in Cases AUTH/2207/2/09 and AUTH/2235/5/09 it was taken up by the Director as it was the Authority's responsibility to ensure compliance with undertakings.

Cephalon stated that it had a serious concern relating to Case AUTH/2235/5/09, in which materials were ruled to be in breach of the undertaking given in Case AUTH/2207/2/09. In Case AUTH/2235/5/09 the Panel ruled a breach of Clause 2 and had reported ProStrakan to the Code of Practice Appeal Board.

Cephalon alleged that unfortunately, the advertisement that had been part of the re-issued campaign in Case AUTH/2235/5/09 had been re-published in the BMJ.

Cephalon was told about the ruling in Case AUTH/2235/5/09 on 23 June 2009. It appeared that ProStrakan had failed to ensure that all materials were withdrawn as required by the undertaking. Sufficient time had elapsed to allow ProStrakan to halt any printing of previously purchased advertising space in the BMJ.

The detailed response from ProStrakan is given below.

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 the future. It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that in Case AUTH/2207/2/09 the claim at issue, 'Rapid relief of breakthrough cancer pain from 10 minutes', which although based on data from a study was inconsistent with the summary of product characteristics (SPC). The SPC stated that 'if adequate analgesia is not obtained within 15-30 minutes of administration of a single sublingual tablet, a second 100 microgram tablet may be administered'. The Panel had ruled a breach of the Code.

In Case AUTH/2235/5/09 the claims at issue were 'To hell and back in minutes' and that Abstral 'Acts

in minutes'. The Panel considered that most readers would not consider 'in minutes' to be as long as 15 minutes. The Abstral SPC was specific with regard to times whereas the advertisement left it to the reader's judgement. The depiction of only three faces of a woman showing the transition from pain to relief, and the accompanying claim 'Dissolves in seconds' added to the impression that Abstral acted quickly. The Panel considered that by not giving more information as to the time Abstral took to act the claims 'Acts in minutes' and 'To hell and back in minutes' were misleading and inconsistent with the SPC. Breaches of the Code were ruled. The Panel was concerned that new material had been developed which might imply to some readers an even quicker time to action than the 10 minute claim previously ruled in breach.

The Panel considered that although there were some differences between the two cases, the claims at issue appeared to show a complete disregard for the previous ruling and were sufficiently similar to be covered by the undertaking previously given. High standards had not been maintained and the failure to comply with the undertaking reduced confidence in and brought discredit upon the pharmaceutical industry. Breaches of the Code were ruled including Clause 2. The Panel had also reported ProStrakan to the Appeal Board.

Turning to the case now at issue, Case AUTH/2268/9/09, the Panel noted that the advertisement in question in Case AUTH/2235/5/09 had been re-used in the BMJ on 12 September. The Panel ruled a breach of the Code. The Panel noted that ProStrakan's agent, had emailed a number of journals to inform them that the advertisement and related materials should not be used. It was not stated why the advertisement had been withdrawn and nor, with one exception for a journal in which advertising was pending, had ProStrakan or its agent requested written confirmation that the email had been received, the advertisement withdrawn and file copies destroyed. Thus the Panel did not consider that ProStrakan's procedures for withdrawing material were sufficiently robust and so in that regard high standards had not been maintained. A breach of the Code was ruled.

The Panel considered that ProStrakan had made some effort to comply with its undertaking and although its procedures should have been more robust, it had been badly let down by the BMJ. Asking all publishers for confirmation that emails had been received and that material had been destroyed/deleted might have avoided the

**problem. Informing publishers why material was being withdrawn would emphasise the need to comply with the withdrawal notice. On balance, however the Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 of the Code.**

Cephalon (UK) Limited complained about an Abstral (sublingual fentanyl citrate) advertisement (ref MO17/0134) issued by ProStrakan which appeared in the BMJ 12 September.

As the complaint alleged a breach of the undertakings given in Cases AUTH/2207/2/09 and AUTH/2235/5/09 it was taken up by the Director as it was the Authority's responsibility to ensure compliance with undertakings.

## COMPLAINT

Cephalon stated that it had a serious concern relating to Case AUTH/2235/5/09, in which materials were ruled to be in breach of the undertaking given in Case AUTH/2207/2/09. In Case AUTH/2235/5/09 the Panel ruled a breach of Clause 2 and had reported ProStrakan to the Code of Practice Appeal Board.

Cephalon alleged that unfortunately, the advertisement that had been part of the re-issued campaign in Case AUTH/2235/5/09 was published in the BMJ on 12 September 2009. This appeared to be not only a breach of the undertaking given in Case AUTH/2207/2/09, but also in breach of that given in Case AUTH/2235/5/09. Cephalon alleged breaches of Clause 25 of the Code.

Cephalon was told about the ruling in Case AUTH/2235/5/09 on 23 June 2009. It appeared that ProStrakan had failed to ensure that all materials were withdrawn as required by the undertaking. Sufficient time had elapsed to allow ProStrakan to halt any printing of previously purchased advertising space in the BMJ.

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ProStrakan was asked to comment in relation to Clauses 2 and 9.1 of the Code in addition to Clause 25 as cited by Cephalon.

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## RESPONSE

ProStrakan understood the significance of an undertaking and was extremely concerned by the publication of the advertisement. ProStrakan explained that it used an agency to buy its advertising space, an advertising agency to manage the placement of the original advertisement and a different advertising agency for the management of a new advertisement.

The events following Case AUTH/2235/5/09 were as follows:

- 23 June 2009. The Authority notified ProStrakan of the outcome of Case AUTH/2235/5/09
  - 24 June. ProStrakan telephoned the advertising agency to discuss the ruling and clarify the need for immediate withdrawal of the advertisement in question. At a meeting with the buying agency ProStrakan made it clear that all advertising in all journals for July and August was to be cancelled.
  - 25 June. ProStrakan emailed the buying agency to confirm that the only pending advertisement, in the August edition of Pain, should be cancelled. The publishers of Pain confirmed that the Abstral materials had been deleted.
  - 26 June. The advertising agency emailed all affected journals, informing them that the advertisement and related materials should not be used and must be deleted from systems and that new copy would be supplied in due course. The message was sent to the BMJ.
  - 30 July. The new advertising agency sent new artwork to the BMJ for the September issue.
  - 16 September. ProStrakan discovered the withdrawn advertisement in the 12 September edition of the BMJ and immediately contacted the PMCPA to report the discovery. ProStrakan initiated an investigation via its buying agency, which contacted the BMJ. The BMJ wrote to ProStrakan's buying agency acknowledging that the advertisement was out of date and had been replaced by new copy sent on 30 July 2009 by the new advertising agency. The BMJ also stated that the use of the incorrect advertisement was due to an issue at the BMJ.
- ProStrakan also contacted all UK and international journals, via its agents, to ensure that all journals had received and understood the withdrawal notification and also that they had received the new artwork. All journals confirmed withdrawal had occurred and that new artwork was in place.
- 17 September. ProStrakan wrote to the BMJ to highlight the serious nature of the error and request details of the original withdrawal and receipt of new artwork.
  - 18 September. Initial response from the BMJ was received.
  - 25 September. The BMJ responded in full.
  - 29 September. ProStrakan contacted the BMJ to request the results of the investigation into the error and seek assurances that appropriate remedial action had been taken.
  - 30 September. The BMJ responded with details of its investigation and corrective actions taken.

ProStrakan submitted that it had taken three key

steps to ensure that the advertisement was not used again. Firstly, a clear withdrawal notification was promptly issued to all journals. Secondly, ProStrakan checked with its agents to identify any pending advertising that used the withdrawn material; this revealed that the August edition of Pain was the only journal affected. Notification of destruction was immediately sought and received from the publishers. Thirdly, new advertising copy was issued and sent to the BMJ and other journals.

ProStrakan submitted that the BMJ had admitted serious failings on its part, both in the withdrawal of the advertisement and the use of new copy. The BMJ accepted that the appropriate individual with relevant responsibility received a timely, clear message about withdrawal. This was the usual method for notification of withdrawal, used by other clients, and should not have required any further action on the part of ProStrakan. Similarly, the new advertising copy was sent to the appropriate individuals at the BMJ.

ProStrakan submitted that it acted immediately on discovering the advertisement and contacted the PMCPA to report the matter. The BMJ was contacted to initiate an investigation. ProStrakan's agents wrote to all UK and European journals that had received Abstral copy to confirm receipt of withdrawal notification, destruction of affected materials and receipt of new advertising copy. All journals stated that they had complied with the original instruction and were using new copy.

ProStrakan acknowledged that, under the Code, it was wholly responsible for the actions of its agents and third parties. ProStrakan accepted that the initial notification to the BMJ should have made it clear that the advertisement was being withdrawn due to a breach of the Code. This notification should have also included more detail about the affected advertisement, particularly the number of iterations and scheduled dates of use. Additionally, ProStrakan should have sought written confirmation from the BMJ that the advertisement had been withdrawn and any copies destroyed or deleted. ProStrakan noted that it was currently reviewing and updating its Code compliance procedures and would be audited by the PMCPA in January 2010. ProStrakan knew its procedures in this area needed to be strengthened and would ensure that lessons learned from this incident were incorporated into its processes.

ProStrakan submitted that the BMJ had established that the root cause of this issue was human error. ProStrakan did not anticipate that a high-profile journal such as the BMJ would fail to act on a clear withdrawal notice and then compound that error by failing to use new advertising material. ProStrakan had sought and received assurances from the BMJ that its processes had been changed to protect against a similar problem in future.

ProStrakan was extremely disappointed that this situation had arisen and it would take all measures

necessary to ensure it did not recur.

## 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 the future. It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that in Case AUTH/2207/2/09 the claim at issue, 'Rapid relief of breakthrough cancer pain from 10 minutes', which although based on data from a study was inconsistent with the summary of product characteristics (SPC). The SPC stated that 'if adequate analgesia is not obtained within 15-30 minutes of administration of a single sublingual tablet, a second 100 microgram tablet may be administered'. The Panel had ruled a breach of Clause 3.2 of the Code.

In Case AUTH/2235/5/09 the claims at issue were 'To hell and back in minutes' and that Abstral 'Acts in minutes'. The Panel considered that most readers would not consider 'in minutes' to be as long as 15 minutes. The Abstral SPC was specific with regard to times whereas the advertisement left it to the reader's judgement. The depiction of only three faces of a woman showing the transition from pain to relief, and the accompanying claim 'Dissolves in seconds' added to the impression that Abstral acted quickly. The Panel considered that by not giving more information as to the time Abstral took to act the claims 'Acts in minutes' and 'To hell and back in minutes' were misleading and in breach of Clause 7.2. A breach of Clause 3.2 was also ruled due to the claims' inconsistency with the SPC. The Panel was concerned that new material had been developed which might imply to some readers an even quicker time to action than the 10 minute claim previously ruled in breach.

The Panel considered that although there were some differences between the two cases, the claims at issue appeared to show a complete disregard for the previous ruling and were sufficiently similar to be covered by the undertaking previously given. A breach of Clause 25 was ruled. High standards had not been maintained and the failure to comply with the undertaking reduced confidence in and brought discredit upon the pharmaceutical industry. Breaches of Clauses 9.1 and 2 were ruled. The Panel had also reported ProStrakan to the Appeal Board.

Turning to the case now at issue, Case AUTH/2268/9/09, the Panel noted that the advertisement in question in Case AUTH/2235/5/09 had been re-used in the BMJ on 12 September. The Panel ruled a breach of Clause 25 of the Code. The Panel noted that ProStrakan's advertising agency had emailed a number of journals to inform them that the advertisement and related materials should not be used. It was not stated why the advertisement had been withdrawn and nor, with one exception for a journal in which advertising was

pending, had ProStrakan or its agent requested written confirmation that the email had been received, the advertisement withdrawn and file copies destroyed. Thus the Panel did not consider that ProStrakan's procedures for withdrawing material were sufficiently robust and so in that regard high standards had not been maintained. A breach of Clause 9.1 of the Code was ruled.

The Panel considered that ProStrakan had made some effort to comply with its undertaking and although its procedures should have been more robust, it had been badly let down by the BMJ. Asking all publishers for confirmation that emails

had been received and that material had been destroyed/deleted might have avoided the problem. Informing publishers why material was being withdrawn would emphasise the need to comply with the withdrawal notice. On balance, however the Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 of the Code.

<b>Complaint received</b>	<b>16 September 2009</b>
<b>Case completed</b>	<b>30 October 2009</b>

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