

VOLUNTARY ADMISSION BY PROCTOR & GAMBLE

Breach of undertaking

Procter & Gamble voluntarily admitted a breach of the Code in that an exhibition guide, which should have been withdrawn pursuant to Case AUTH/2267/9/09, was put into the delegate bags for an international congress held in the UK.

The Authority's Constitution and Procedure provided that a voluntary admission should be treated 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 reuse of material previously ruled in breach was a serious matter and the admission was accordingly treated as a complaint.

Procter & Gamble explained that in Case AUTH/2267/9/09, the strapline 'Confidence in Colitis' was ruled in breach of the Code. As a result, Procter & Gamble immediately recalled and destroyed all relevant materials. After executing a robust and thorough recall process, Procter & Gamble was confident that as per the undertaking, signed on 28 October, these materials were last used on 10 November. However on 18 November, it was discovered that owing to an individual human error the exhibition guide, which contained an Asacol advertisement with the strapline 'Confidence in Colitis', had been overlooked. The exhibition guide had been approved prior to the Panel's ruling but was printed after the Panel's ruling and placed in delegate bags ready for the congress which opened on 21 November.

As soon as it knew of the error Procter & Gamble tried to stop the exhibition guide being distributed. The conference organiser was immediately informed of the situation. Agency workers were allowed into the exhibition centre overnight to remove the material from the delegate bags. No access to the delegate bags was allowed whilst the corrective action was being undertaken and the conference organiser oversaw the removal of material in order to ensure that there was no mixing of 'old' and 'amended' delegate bags. Two company employees were sent to the conference venue the next morning (20 November) to ensure that all of the exhibition guides in question were removed and destroyed. However a sample audit of approximately 5,000 out of the 14,000 delegate bags showed that a very small minority of delegate bags still contained the exhibition guides at issue.

Procter & Gamble acknowledged that the undertaking was an important document and that this incident was a significant error on its behalf, hence the actions that were immediately implemented as soon as it knew about the situation. As a matter of high priority its standard

operating procedure for the recall of promotional materials would be revisited and revised to ensure that all employees followed procedures correctly so incidences such as this one could never happen again.

The detailed response from Procter & Gamble is given below.

The Panel noted that Procter & Gamble had agreed to the printing of the exhibition guide on 15 October and printing commenced on 27 October. Procter & Gamble had been advised of the Panel's ruling in Case AUTH/2267/9/09 on 20 October and the company signed the undertaking on 28 October. The last use of the material at issue was to be 10 November.

The Panel was concerned that the exhibition guide was not included on a job bag tracker spreadsheet. This appeared to be the root cause of the problem. No details were given about how the error came to light on 18 November. The Panel considered that once the error had been identified, Procter & Gamble had made every effort to withdraw the material. Nonetheless when the conference delegates started to arrive on 20 November a small number of delegate bags still contained the exhibition guide in question.

The Panel considered that Procter & Gamble had breached its undertaking and a breach of the Code was ruled as acknowledged by the company. By failing to list the material on the job bag tracker spreadsheet the Panel considered that high standards had not been maintained and a breach of the Code was ruled as acknowledged by Procter & Gamble.

Notwithstanding the considerable action taken by Procter & Gamble to withdraw the material, together with the timing of the printing of the exhibition guide and the provision of the undertaking, the Panel considered that the failure to list the material on the job bag tracker spreadsheet and the resultant distribution of a small number of the exhibition guides reduced confidence in the pharmaceutical industry. A breach of Clause 2 of the Code was ruled.

Procter & Gamble Pharmaceuticals UK, Limited voluntarily admitted a breach of the Code in that an exhibition guide (ref AS8112) which should have been withdrawn pursuant to Case AUTH/2267/9/09 was put into the delegate bags for Gastro 2009, a large international congress held in the UK.

The action to be taken in relation to a voluntary

admission by a company was set out in Paragraph 5.4 of the Authority's 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 reuse of material previously ruled in breach was a serious matter and the admission was accordingly treated as a complaint.

COMPLAINT

Procter & Gamble explained that following notification of the Panel's ruling in Case AUTH/2267/9/09, dated 20 October 2009, it was found in breach of Clause 3.2 in relation to the strapline 'Confidence in Colitis'. Other breaches were also found. As a result, Procter & Gamble immediately implemented its standard operating procedure (SOP) for the recall and destruction of all promotional materials that were subject to these rulings.

After executing a robust and thorough recall process, Procter & Gamble was confident that all affected materials had been successfully accounted for and thus no longer in promotional use. As per the undertaking, signed on 28 October, these materials were last used on 10 November.

However at close of business Wednesday, 18 November, it was discovered that owing to an individual human error one item had been overlooked ie the exhibition guide at issue that had been sponsored by Procter & Gamble. The exhibition guide contained an Asacol advertisement with the strapline 'Confidence in Colitis'. The exhibition guide had been approved by Procter & Gamble prior to the Panel's ruling.

Unfortunately, the exhibition guide was inadvertently printed after the Panel's ruling and placed in the delegate bags to be distributed at the congress which opened on 21 November.

As soon as this error had been identified, Procter & Gamble took the matter extremely seriously and did the following to prevent any of the exhibition guides being distributed.

- The conference organiser was contacted immediately to tell them about the situation and to understand the logistics involved (eg location of delegate bags, etc).
- An agency provided 27 people by 12.30 on 19 November (increasing to 70 people by 17.00) to work overnight and remove the material from the delegate bags.
- The agency workers were given access to an isolated area of the exhibition centre to ensure no public access to the delegate bags whilst the corrective action was being undertaken.
- The conference organiser oversaw the removal of material in order to ensure that there was no mixing of 'old' and 'amended' delegate bags.
- Two Procter & Gamble employees were sent to

the conference venue the next morning (20 November) to ensure that all of the exhibition guides in question were removed and destroyed by the agency staff. They also sampled approximately 5,000 out of the 14,000 delegate bags to assess how thorough the operation was.

However despite all of Procter & Gamble's efforts to remove the exhibition guides, on Monday, 23 November it was apparent that, according to its sample audit, a very small minority of delegate bags still contained them.

Procter & Gamble acknowledged that the undertaking was an important document and that this incident was a significant error on its behalf, hence the actions that were immediately implemented as soon as it knew about the situation.

Procter & Gamble noted that the company was acquired by Warner Chilcott UK Ltd on 30 October 2009. As a matter of high priority for the new company, all SOP training processes, including the one for the recall of promotional materials, would be revisited and revised to ensure that all employees followed procedures correctly so incidences such as this one could never happen again. Procter & Gamble would also look to see if the SOP could be made even clearer in terms of instructions to employees.

When writing to Procter & Gamble the Authority asked it to comment in relation to Clauses 2, 9.1 and 25 of the Code.

RESPONSE

Procter & Gamble stated that following notification of the Panel's ruling of 20 October in Case AUTH/2267/9/09, it was found in breach of the Code on three counts: Clause 3.2 relating to the strapline 'Confidence in Colitis' and two other breaches were ruled. Procter & Gamble accepted the breaches and immediately implemented its SOP for the recall and destruction of all promotional materials that were subject to these rulings. This process included an email being sent to the sales force on the day the undertaking was signed (28 October). The email was sent with high importance, a return receipt, and was preceded by a text message sent earlier that day.

After executing what it believed to be a robust and thorough recall process, Procter & Gamble was confident that all affected materials had been successfully accounted for and subsequently no longer in promotional use. As per the undertaking, these materials were last used on 10 November. However at approximately 13:30 on 18 November, it was discovered that the exhibition guide for Gastro 2009 (AS8112; Date of Preparation Oct 2009) had been overlooked. Gastro 2009 was a large international conference held in the UK from 21-25 November. The four page exhibition guide was sponsored by Procter & Gamble. The first page listed all the exhibitors, the inside double spread

showed a map of where all the exhibitors could be found within the conference hall. The back page had an Asacol advertisement which included the strapline 'Confidence in Colitis' previously ruled in breach.

The exhibition guide had been approved and certified on 14 October, ie before the Panel had concluded its rulings in Case AUTH/2267/9/09. On 14 October Procter & Gamble gave its media agency permission to print the guides. On 15 October the media agency sent the approved map to the Gastro 2009 conference organisers for printing. Again this was before both the case rulings and the undertaking was signed by Procter & Gamble on 28 October. Printing of the maps began on 27 October ie before the undertaking was signed.

Unfortunately, the exhibition guide was not identified in the recall process; this was because the material was not included in the Asacol job bag tracker, an internal spreadsheet designed to document all promotional materials relating to Asacol. The recall SOP made it clear and upfront that all items subject to an Authority ruling should be identified. However this was totally dependent on individuals accurately populating the job bag tracker on an on-going basis. Procter & Gamble had already identified this matter as an urgent training gap and as a direct consequence all personnel accountable in the recall SOP, as well as all other relevant SOPs, were retrained on 9 December, with this matter as a poignant example.

As a result of this oversight, 14,000 exhibition guides were in print when the undertaking was signed.

As soon as it knew about the error, Procter & Gamble took the matter seriously and put the following steps into place to prevent any of the exhibition guides being distributed as set out above. Procter & Gamble repeated them below, with further detail, to provide clarity as to the steps taken to rectify the error:

- The conference organisers were advised of the situation by telephone and email and asked about the logistics involved (eg location of delegate bags, etc). Procter & Gamble liaised with the organiser to make the necessary arrangements for the removal of the exhibition guide. An agency provided 27 people by 12:30 on 19 November (increasing to 70 people by 17:00) to work overnight and remove the material from the delegate bags. The agency workers were given access to a designated area of the exhibition centre to ensure no public access to the delegate bags whilst the corrective action was being undertaken.
- The conference organiser oversaw the removal of material in order to ensure that there was no mixing of 'old' and 'amended' delegate bags.
- Two Procter & Gamble employees went to the venue the next morning (20 November), to check that all the exhibition guides had been removed

from the delegate bags. They sampled 5,000 out of the 14,000 bags to assess how thorough the operation had been.

However, despite all of Procter & Gamble's efforts to remove the exhibition guide, on Friday 20 November when conference delegates began to arrive, it was apparent that, according to Procter & Gamble's sample audit, a small minority, estimated at approximately < 2%, of delegate bags still contained the exhibition guide.

Procter & Gamble assured the Panel that it had taken this matter extremely seriously and as a top priority for the company the SOP for the recall of promotional material was being appraised. The aim being to ensure the entire process was as robust and thorough as it needed to be. Procter & Gamble had therefore conducted refresher training on all relevant SOPs, on 9 December, for all personnel accountable in these SOPs.

Procter & Gamble was fully committed to comply with its undertaking in relation to Case AUTH/2267/9/09 and realised the importance of this document. This was why Procter & Gamble told the Authority immediately it became apparent that, unfortunately despite all its efforts to stop the exhibition guide being distributed at Gastro 2009, there remained a small chance that not all of the guides had been removed from the 14,000 delegate bags.

Procter & Gamble acknowledged that the requirements for Clause 25 had not been fulfilled and that failing to prevent any of the exhibition guides from being distributed after the undertaking had been signed indicated that high standards had not been met. However Procter & Gamble hoped the Panel would consider that the overall effort to rectify the error, and the urgency behind this effort, was testimony to the company's professional and responsible approach to the matter. This coupled with the fact that on 21 November, when Gastro 2009 opened, only an extremely small number of delegate bags might have contained the incorrect exhibition guide. Procter & Gamble therefore believed its actions, as described above, had not resulted in an incident that had brought the entire pharmaceutical industry into disrepute.

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 and that they provided full and accurate details of the last use of material in breach.

The Panel noted that Procter & Gamble had agreed to the printing of the exhibition guide on 15 October and printing commenced on 27 October. Procter & Gamble had been advised of the Panel's ruling in

Case AUTH/2267/9/09 on 20 October and the company signed the undertaking on 28 October. The last use of the material at issue was to be 10 November.

The Panel was concerned that the exhibition guide was not included on the job bag tracker spreadsheet. This appeared to be the root cause of the problem. No details were given about how the error came to light on 18 November. The Panel considered that once the error had been identified, Procter & Gamble had made every effort to withdraw the material. Nonetheless when the conference delegates started to arrive on 20 November a small number of delegate bags still contained the exhibition guide in question. The Panel considered that Procter & Gamble had breached its undertaking and a breach of Clause 25 was ruled as acknowledged by the company. By failing to list the material on the job bag tracker spreadsheet the Panel considered that high standards had not been maintained and a breach of Clause 9.1 was ruled as acknowledged by Procter & Gamble.

With regard to Clause 2, the Panel considered that the relevant factor was whether the circumstances surrounding the breach of undertaking warranted such a ruling. A company must be satisfied that its

internal control of promotional material was such that, when called upon to provide an undertaking it could be confident that the information so provided was accurate. It was thus essential that any document designed to list all promotional material was accurately populated and always up-to-date. The Panel considered that Procter & Gamble's actions on discovering the error had been exemplary. If the exhibition guide had been identified when the undertaking was provided, Procter & Gamble would have had to withdraw the guide as a consequence of signing that undertaking.

Notwithstanding the considerable action taken by Procter & Gamble to withdraw the material, together with the timing of the printing of the exhibition guide and the provision of the undertaking, the Panel considered that the failure to list the material on the job bag tracker spreadsheet and the resultant distribution of a small number of the exhibition guides reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

Complaint received	23 November 2009
Case completed	25 January 2010
