

VOLUNTARY ADMISSION BY GLAXOSMITHKLINE and ROCHE

Breaches of undertakings

GlaxoSmithKline and Roche voluntarily admitted that they had breached undertakings given in Cases AUTH/1971/3/07 and AUTH/1972/3/07 in relation to the promotion of Bonviva (ibandronic acid). The companies had, in good faith, given an undertaking not to use the claim 'Building Bones' after June 13.

In line with standard operating procedures (SOPs), the sales force was told to withdraw all promotional materials with the 'Building Bones' claim and return them to head office for destruction. Similarly all agencies and publishing companies were told to withdraw, destroy and to stop using the only Bonviva advertisement running at that time which carried the claim.

Email confirmation of the above actions was received from all the relevant agencies and publishing companies. Roche and GlaxoSmithKline were satisfied that all third parties had taken all steps necessary to prevent the claim being used. The companies were thus extremely surprised and disappointed to find an advertisement containing the 'Building Bones' claim in the 20 September issue of Pulse.

Initial investigations revealed that the publishing company for Pulse had published this advertisement despite confirmation that it had withdrawn, destroyed and was to stop using existing copies of the Bonviva advertisement containing the claim.

Roche and GlaxoSmithKline deeply regretted that this situation had occurred. The companies acknowledged that this had placed them in breach of the undertaking and thus in breach of the Code.

Paragraph 5.4 of the Authority's Constitution and Procedure provided that the Director should treat a voluntary 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 regarded as a serious matter and the admission was accordingly treated as a complaint.

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 Cases AUTH/1971/3/07 and AUTH/1972/3/07 the claim 'Building Bones' for Bonviva was ruled in breach of the Code. Roche and GlaxoSmithKline provided the requisite

undertakings in June 2007 stating that the final use of, *inter alia*, the journal advertisement was 13 June 2007. Pulse had re-published the advertisement on 20 September 2007.

The Panel noted that an email from a senior media buyer to the publishers of Pulse gave clear instructions not to run the latest Bonviva copy due to required amendments to bring it in line with ABPI guidelines and to destroy existing copy and confirm receipt of the email. New copy was being developed and would be distributed as soon as possible. The publishers of Pulse confirmed that the email had been sent to the production department and existing copy would no longer be used. It did not, however, confirm that relevant copy would be destroyed, as requested. Most other recipients of the email referred to destruction of the material in their response. Following investigation with the publishers of Pulse it appeared that the advertisement was removed from the last 3-4 insertion files but copy remained on the system for a year. The procedure was that a note was put on the file clearly highlighting that the copy was not to be used again. In this instance the production contact had looked back several months beyond the last Bonviva insertion to repeat copy rather than chasing new artwork.

The Panel considered that GlaxoSmithKline and Roche had taken all possible steps to comply with its undertaking. The companies had been badly let down by Pulse. The Panel had no option but to rule a breach of the Code as Pulse's failure to comply with the instructions meant that GlaxoSmithKline and Roche had breached their undertakings as acknowledged by both companies. In the circumstances the Panel did not consider that GlaxoSmithKline and Roche had failed to maintain high standards or that they had brought discredit upon, or reduced confidence in, the industry.

GlaxoSmithKline UK Ltd and Roche Products Limited voluntarily admitted that they had breached undertakings and assurances that they had given in Cases AUTH/1971/3/07 and AUTH/1972/3/07 in relation to the promotion of Bonviva (ibandronic acid).

COMPLAINT

Writing on behalf of both companies, GlaxoSmithKline advised the Authority of a likely breach of the Code in relation to Cases AUTH/1971/3/07 and AUTH/1972/3/07.

GlaxoSmithKline explained that the companies had unsuccessfully appealed the use of the strapline,

'Building Bones', in the above cases and accepted the Code of Practice Appeal Board's rulings of breaches of Clauses 7.2 and 7.4. The undertaking stated that the claim would not be used after 13 June. Both Roche and GlaxoSmithKline took an undertaking extremely seriously and took all necessary steps to ensure that the claim would not be used again in any form.

In line with company standard operating procedures (SOPs), the sales force was told to withdraw all promotional materials with the claim and these materials were returned to head office and destroyed. Similarly all agencies and publishing companies were told to withdraw, destroy and to stop using the only Bonviva advertisement running at that time which carried the 'Building Bones' claim.

Email confirmation of the above actions was received from all the relevant agencies and publishing companies. Roche and GlaxoSmithKline were satisfied that all third parties had confirmed to them and taken all steps necessary to prevent this claim from being used.

Given the above, the companies were thus extremely surprised and disappointed to find an advertisement containing the 'Building Bones' claim in the 20 September issue of Pulse. An investigation was initiated on the same day to find the source of the advertisement.

Initial investigations discovered that the publishing company for Pulse had published this advertisement despite confirmation that it had withdrawn, destroyed and was to stop using existing copies of the Bonviva advertisement containing the 'Building Bones' claim. Further investigations with the publishers to better understand why the material was not destroyed as requested were ongoing.

Roche and GlaxoSmithKline deeply regretted that this situation had occurred through the inadvertent use of an old advertisement by a publishing company despite Roche and GlaxoSmithKline acting in line with company SOPs and confirming with each supplier that the required actions had been taken. The companies acknowledged that this had placed them in breach of the undertaking signed in good faith and thus in breach of the Code.

Paragraph 5.4 of the Authority's Constitution and Procedure provided that the Director should treat a voluntary 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 regarded as a serious matter and the admission was accordingly treated as a complaint.

When writing to GlaxoSmithKline and Roche, the Authority asked them to respond in relation to Clauses 2, 9.1 and 22 of the Code.

RESPONSE

On behalf of both companies, GlaxoSmithKline

reiterated the course of events as detailed above.

GlaxoSmithKline submitted that, as previously mentioned, the media agency had received emails from all the publishing companies to withdraw, destroy and stop using the only Bonviva advertisement which contained the 'Building Bones' claim at that time. This included confirmation from Pulse's publishers on 26 May.

Investigation within the publishing company revealed a fault in its publication process. It was found that removing the copy of the advertisement from records erased it from the last three or four insertion files. The copy of the advertisement did not leave the system for a year. A note was also put on the copy file highlighting that it should never be used again.

However, on this occasion, the production contact for the publishing company had looked back several months beyond the last Bonviva advertisement insertion to repeat the copy of their own accord in contravention of the explicit instructions given. There was no instruction to do this from either Roche or GlaxoSmithKline. As a result, the Bonviva advertisement with the 'Building Bones' claim was published in the 20 September issue of Pulse.

The publishers were deeply apologetic for the error and the fact that this had caused Roche and GlaxoSmithKline to be in breach of their undertakings. The companies were equally disturbed that, despite a written guarantee from the publishing company, this had occurred. The publishing company had since taken steps to ensure that such a mistake would not occur again.

Roche and GlaxoSmithKline deeply regretted that this situation had occurred through the inadvertent use of an old advertisement by a publishing company, which had previously confirmed by email that the advertisement had been withdrawn, destroyed and stopped from being used.

Roche and GlaxoSmithKline had taken extensive steps to prevent this from happening, acting in line with company procedures and receiving written confirmation from each supplier that the required actions had been taken.

Roche and GlaxoSmithKline were confident that they had a robust system in place to withdraw promotional material and had demonstrated this in the course of this response. Nevertheless, both companies recognised that under the Code they were responsible for the actions of their agents. As such they regretfully admitted a breach of Clause 22 as an advertisement previously ruled in breach of the Code had reappeared. This was despite compliance with their own SOPs which included the need for 100% confirmation from all parties that they had taken the required actions to prevent this occurring.

Given that the publishing company had admitted that the failing was entirely its and had taken remedial action to prevent recurrences, and that neither Roche nor GlaxoSmithKline procedures were at fault in this

case, they did not believe that they had incurred breaches of Clauses 9.1 or 2.

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 Cases AUTH/1971/3/07 and AUTH/1972/3/07 the Appeal Board had ruled that the claim 'Building Bones' for Bonviva was in breach of the Code. Roche and GlaxoSmithKline provided the requisite undertakings in June 2007 stating that the final use of, *inter alia*, the journal advertisement was 13 June 2007. Pulse had re-published the advertisement on 20 September 2007.

The Panel noted that an email from a senior media buyer to the publishers of Pulse gave clear instructions not to run the latest Bonviva copy due to required amendments to bring it in line with ABPI guidelines and to destroy existing copy and confirm receipt of the email. New copy was being developed and would be distributed as soon as possible. The publishers confirmed that the email had been sent to the production department and existing copy would no longer be used. It did not, however, confirm that relevant copy would be destroyed, as requested. Most

other recipients of the email referred to destruction of the material in their response. Following investigation with the publishers it appeared that the advertisement was removed from the last 3-4 insertion files but copy remained on the system for a year. The procedure was that a note was put on the file clearly highlighting that the copy was not to be used again. In this instance the production contact had looked back several months beyond the last Bonviva insertion to repeat copy rather than chasing new artwork.

The Panel considered that GlaxoSmithKline and Roche had taken all possible steps to comply with its undertaking. The companies had been badly let down by Pulse. The Panel had no option but to rule a breach of Clause 22 as Pulse's failure to comply with the instructions meant that GlaxoSmithKline and Roche had breached their undertakings as acknowledged by both companies. In the circumstances the Panel did not consider that GlaxoSmithKline and Roche had failed to maintain high standards or that they had brought discredit upon, or reduced confidence in, the industry. Thus no breach of Clauses 2 and 9.1 was ruled.

Complaint received	27 September 2007
Cases completed	
Case AUTH/2049/9/07	25 October 2007
Case AUTH/2050/9/07	29 October 2007
