

VOLUNTARY ADMISSION BY DAIICHI-SANKYO

Breach of undertaking

Daiichi-Sankyo (formerly Sankyo) voluntarily advised the Authority that an advertisement which had been ruled in breach of the Code in Case AUTH/1787/12/05 had reappeared despite the company giving an undertaking not to use it again.

As the admission related to a breach of undertaking, which was a serious matter, it was treated as a complaint under the Code in accordance with the Authority's Constitution and Procedure. Daiichi-Sankyo provided a detailed explanation as to what had happened.

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/1787/12/05 it had considered that an advertisement for Olmetec was closely similar to a previous one which it had ruled in breach of the Code such that Sankyo had not complied with its undertaking. Breaches of the Code, including a breach of Clause 2, were ruled. In the case now at issue, Case AUTH/1866/7/06, the advertisement considered in Case AUTH/1787/12/05 had been published again. The undertaking in Case AUTH/1787/12/05 was signed on 16 February 2006.

Between signing the undertaking in February and the advertisement at issue being published in error in June, Sankyo had changed its advertising agency. The Panel, however, considered that Sankyo should have quickly traced and withdrawn all versions of the advertisement such that when the new agency took over there were no old advertisements in existence. On signing an undertaking it was beholden upon companies to rapidly ensure that no materials which were in breach of the Code were used again, no matter in what format they were held or by whom. The guidelines on company procedures relating to the Code advised companies to keep written records of action taken to withdraw material.

The Panel noted that in correspondence from Sankyo to its various agencies just prior to the signing of the undertaking, there was no clear instruction that old versions of the Olmetec advertisement should be destroyed or returned to the company. The Panel did not consider that merely telling people not to use material ruled in breach of the Code was sufficient – copies should be destroyed. In that regard the Panel considered that Sankyo had not taken all possible steps to comply with its undertaking. High standards had not been maintained. Breaches of the Code were ruled. The Panel further considered that Sankyo, by not doing all that it could have done to comply with its undertaking had brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

Daiichi-Sankyo UK Ltd voluntarily advised the Authority that an advertisement (OLM 188.1B) which had been ruled in breach of the Code in Case AUTH/1787/12/05 had appeared in the May/June

edition of the British Journal of Cardiology. Daiichi-Sankyo had given an undertaking not to use the advertisement after 19 February 2006.

COMPLAINT

As the matter related to a breach of undertaking it was sufficiently serious for it to be taken up and dealt with as a formal complaint under the Code (Paragraph 5.4 of the Constitution and Procedure). Daiichi-Sankyo was asked to respond in relation to Clauses 2, 9.1 and 22 of the Code.

RESPONSE

Daiichi-Sankyo stated that it first knew of the advertisement's appearance on 29 June and it alerted the Authority informally of this on 30 June and had since conducted a thorough investigation to identify how this occurred.

Daiichi-Sankyo submitted that following the ruling in Case AUTH/1787/12/05, it had stopped working with one advertising agency and started working with another. Investigations had thus involved the previous advertising agency, the current advertising agency and the media buyer. The previous agency had produced the advertisement found in breach in Case AUTH/1787/12/05 and was involved in the development of a new advertisement (version 1). This new advertisement was subsequently taken over by the new agency and adapted (version 2). The new advertising agency was not involved with the advertising that had been found in breach in Case AUTH/1787/12/05.

Daiichi-Sankyo submitted that the advertising agency was responsible for the production of promotional material and the media buyer was responsible for placement once approved by the company. The media buyer would thus ask the agency for 'an approved' advertisement in order to hit a publication date and the agency in turn would ask the company for an approved advertisement so that it could provide the necessary artwork to the media buyer in order for this to be sent to a publisher by the required deadline.

Daiichi-Sankyo provided copies of correspondence confirming relevant actions and instructions, including a detailed timetable of events from 1 February, when Sankyo received the Panel's ruling in Case AUTH/1787/12/05 and considered appealing, until 11 July when confirmation was received from the new agency that all advertisements were in the current design.

Daiichi-Sankyo submitted that the breach of undertaking had occurred because of the following:

- A failure by the previous agency and/or the media buyer to adhere to the written confirmation

which was provided to Daiichi-Sankyo by ensuring that all journals were informed to cease use of such materials.

There was a difference in the version of events between the previous advertising agency and the media buyer – the media buyer maintained that the responsibility for telling the journals to destroy old copies lay with the advertising agency but the advertising agency maintained that this was not the case and that it was up to the media buyers to inform the journals.

The only consistent documentation Daiichi-Sankyo had between the two parties which confirmed that the appropriate actions had been carried out was that provided on 13 and 15 February and which confirmed that 19 February was the last date of use and all other items had been cancelled.

- An assumption by the new advertising agency that all advertising material with publishers was in the new campaign design and did not feature the previous claims which had been ruled in breach.
- A failure by the new agency to follow process by dealing directly with the publisher instead of using the media buyer.
- A failure of the new advertising agency to check with Daiichi-Sankyo or the media group that the advertisement being re-run complied with the Code.

Daiichi-Sankyo submitted that as a consequence of its findings it had acted in good faith with respect to its undertaking to comply with the ruling in Case AUTH/1787/12/05.

Daiichi-Sankyo submitted that it had sought, received and acted upon written confirmation from the media buyer and previous agency at the time of the ruling and did not foresee the chain of events thereafter or that there would be a breakdown in communication between the previous advertising agency and media buyer.

Daiichi-Sankyo submitted that written assurances from both parties at the time led it to believe that all had been dealt with effectively and that the advertisement would appear for the last time on 19 February. There was no reason to question the process between media buyer and advertising agency at that time. Daiichi-Sankyo was concerned that the new agency had acted beyond its remit by dealing directly with the publisher.

As a consequence Daiichi-Sankyo intended to reinforce clear roles and responsibility into both agency and media buyer contracts and ensure that this series of events could not happen again. A copy of the proposed process was provided.

In addition Daiichi-Sankyo would insist that its media buyer now provided a copy of the advertisement, or identify by code any advertisements before they were re-run.

Daiichi-Sankyo submitted that despite these advertisements having already been signed off and approved at Daiichi-Sankyo, it would insist that it

received notification prior to re-placement of any advertisements and provided the approval for use of such advertisements again.

Daiichi-Sankyo hoped this thorough and rapid investigation and resultant actions demonstrated that due process had been followed and the serious nature with which it viewed this issue. Daiichi-Sankyo sincerely regretted this occurrence but believed that it would not happen again.

In a response to a request for further comment Daiichi-Sankyo noted that it was its own internal procedure which identified the re-publication of the advertisement which had previously been ruled in breach. Furthermore Daiichi-Sankyo's voluntary admission within a day of realising this had happened, followed by a detailed, rapid and subsequent investigation with provision of written documentation submitted to the Authority as a voluntary admission, indicated the seriousness with which it viewed the occurrence. These actions further underlined the serious nature which Daiichi-Sankyo viewed the undertaking previously given and its intention to establish how this occurred and immediately rectify identified issues.

Daiichi-Sankyo submitted that it always intended to treat the breach ruled in Case AUTH/1787/12/05 with respect and to comply with the requirements resulting from the findings.

The undertaking affected all of Daiichi-Sankyo's campaign materials and its established and previously tested process enabled the effective recall and destruction of materials from the entire UK organisation. Furthermore Daiichi-Sankyo was confident that its process for withdrawal of copy was robust and had achieved the required written assurances from its third party clients that ensured compliance with the commitment made to the Authority.

Daiichi-Sankyo submitted that it based its belief in its agencies on a previously successful uneventful withdrawal of advertising copy. Daiichi-Sankyo submitted that therefore the process it had in place was robust and effective and once more used this process to ensure compliance with the undertaking in the expectation of the same successful outcome.

Daiichi-Sankyo submitted that it had told the current advertising agency that the previous advertisement had been withdrawn and had been replaced by 'the man on the platform' campaign. The agency had been authorized to run repeats of 'the man on the platform' execution which was the only currently authorised advertisement. However, the agency did not confirm that the repeat advertisement was the approved copy (man on the platform) when instructing the publisher.

Daiichi-Sankyo submitted that it was very surprised and extremely disappointed when it discovered the re-publication of the previous journal advertisement and it took the immediate action of a voluntary admission.

Following the incident Daiichi-Sankyo submitted that it had implemented, or was in the process of implementing, a number of measures which included:

- Reinforcing clear roles and responsibilities with its advertising agency included in contractual terms and conditions.
- Creation of a standard template letter to be provided by Daiichi-Sankyo in accordance with the roles and responsibilities to agencies in the event of a withdrawal.
- An update to the existing SOP for withdrawal of materials to include the previous two points and the inclusion of an express instruction and confirmation of destruction of all electronic versions to be provided by journals. Furthermore this was to be documented and kept within Daiichi-Sankyo.

Following its detailed review, Daiichi-Sankyo had updated its SOP by providing a written template to the agency to provide to the publishers which would also now include an express instruction for all electronic media to be returned or destroyed from servers. This was a strengthening of the previous process as it was clear that written documentation from the agency had not been forthcoming to support instructions that had been made with regards to electronic media.

Daiichi-Sankyo submitted that while it made every endeavour to comply with its undertaking it was let down by external agencies on this occasion and was therefore accountable for a breach of undertaking (Clause 22). However it submitted that it had maintained the expected high standards throughout (Clause 9.1) and had not brought the industry into disrepute (Clause 2) due to its voluntary admission and prompt, thorough response.

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/1787/12/05 it had considered that an advertisement for Olmetec

was closely similar to a previous one which it had ruled in breach of the Code such that Sankyo had not complied with its undertaking. Breaches of the Code, including a breach of Clause 2, were ruled. In the case now at issue, Case AUTH/1866/7/06, the advertisement considered in Case AUTH/1787/12/05 had been published again. The undertaking in Case AUTH/1787/12/05 was signed 16 February 2006.

Between signing the undertaking in mid February for Case AUTH/1787/12/05 and the advertisement at issue being published in error in June, Sankyo had changed its advertising agency. The Panel, however, considered that Sankyo should have quickly traced and withdrawn all versions of the advertisement such that when the new advertising agency took over there were no old advertisements in existence. On signing an undertaking the Panel considered that it was beholden upon companies to rapidly ensure that no materials which were in breach of the Code were used again, no matter in what format they were held or by whom. The guidelines on company procedures relating to the Code of Practice stated that companies were advised to keep written records of action taken to withdraw material.

The Panel noted that in correspondence from Sankyo to its various agencies just prior to the signing of the undertaking, there was no clear instruction that old versions of the Olmetec advertisement should be destroyed or returned to the company. The Panel did not consider that merely telling people not to use material ruled in breach of the Code was sufficient – copies should be destroyed. In that regard the Panel considered that Sankyo had not taken all possible steps to comply with its undertaking. High standards had not been maintained. The Panel ruled breaches of Clauses 9.1 and 22 of the Code. The Panel further considered that Sankyo, by not doing all that it could have done to comply with its undertaking had brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

Complaint received	13 July 2006
Case completed	29 August 2006